



MATERIAL TRACKING PHASES
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FUNCTIONAL REQUIREMENT SPECIFICATION

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1 Introduction

This document details the requirements of the functions implemented by the phases specific to material tracking. The phases are executed in the Production Execution Client of PharmaSuite.

Each requirement is composed of a name (e.g., Preview mode) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] [\(GID-2668043\)](#).

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as <ul style="list-style-type: none">▪ window and dialog titles▪ menu functions▪ panel, tab, and button names▪ box labels▪ object properties and their values (e.g., status).
Monospaced typeface	Designates code examples.

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2 Recipe Configuration for Material Tracking

This section provides an overview of material tracking within process orders.

2.1 Phases and Structural Context

The phases of material tracking rely on material data provided by their material parameters. They can be run in three very different structural contexts:

- as sequential process where each phase needs to be completed to pass its material data on to the following phase.
- as simultaneous process, where all phases can be concurrently active in different operations and the material data is passed on as soon as it occurs in one of the phases.
- as simultaneous process, where the same phases can be concurrently active in different operations and operators can work on the same material positions, but with different sublots.

The following phases are available:

- Identify material ([GID-2668011](#))
The **Identify material** phase needs to hold all materials to be processed as MFC-relevant material input parameters.
All listed materials and quantities can either be identified during a single phase run or the phase can be placed in a loop or an event-triggered operation and run several times for identifying the materials in several runs of the phase.
- Show GHS data (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] ([GID-2668043](#)))
The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.
The usage of the **Show GHS data** phase during **Material Tracking** is optional.
- Produce material ([GID-2668032](#))
The **Produce material** phase expects the produced material as MFC-relevant material output parameter. It has an external loop so that it can produce sublots of the output material in several runs and different subplot quality statuses. The phase can also be placed in an event-triggered operation. Thus, it is possible to model a process during which a set of sublots is produced, another phase is used to perform another action on the produced sublots, such as placing them on a pallet, and then the next run of the **Produce material** phase is started to produce another set of sublots.
- Load logistic unit (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] ([GID-2668043](#)))
The **Load logistic unit** phase allows an operator to load sublots or a logistic unit onto a target logistic unit.
The usage of the **Load logistic unit** phase during **Material Tracking** is optional.

- Account material ([GID-2668022](#))

The **Account material** phase expects the same materials as input parameters that were processed in the **Identify material** phase. In this case, however, the input parameters are not MFC-relevant, since the phase only calculates the usage quantities of the materials while the actual material flow has taken place earlier in the **Identify material** and **Produce material** phases.

The listed materials can either be accounted during a single phase run or the phase can be placed in a loop or an event-triggered operation to run several times and thus concurrently account the usage quantities of the identified and processed materials.

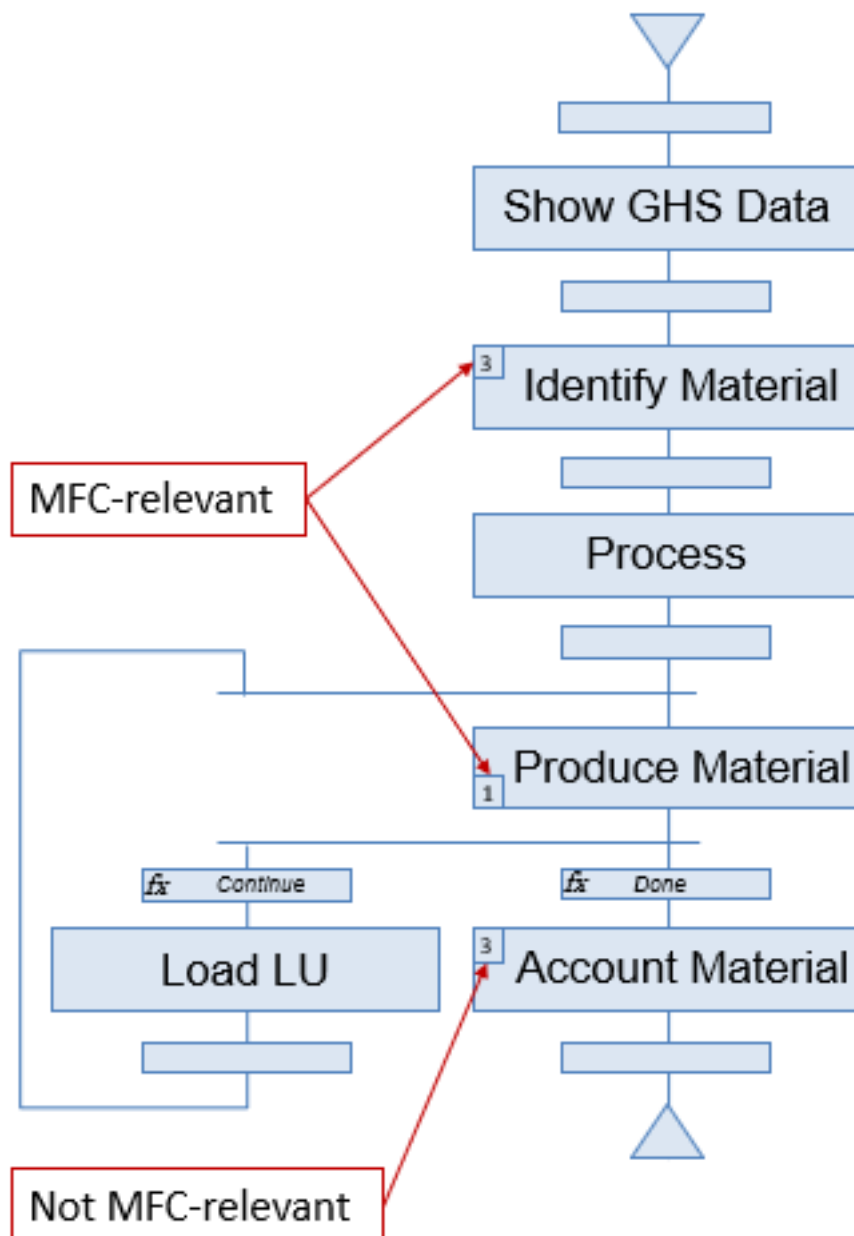


Figure 1: Operation with sequential material tracking

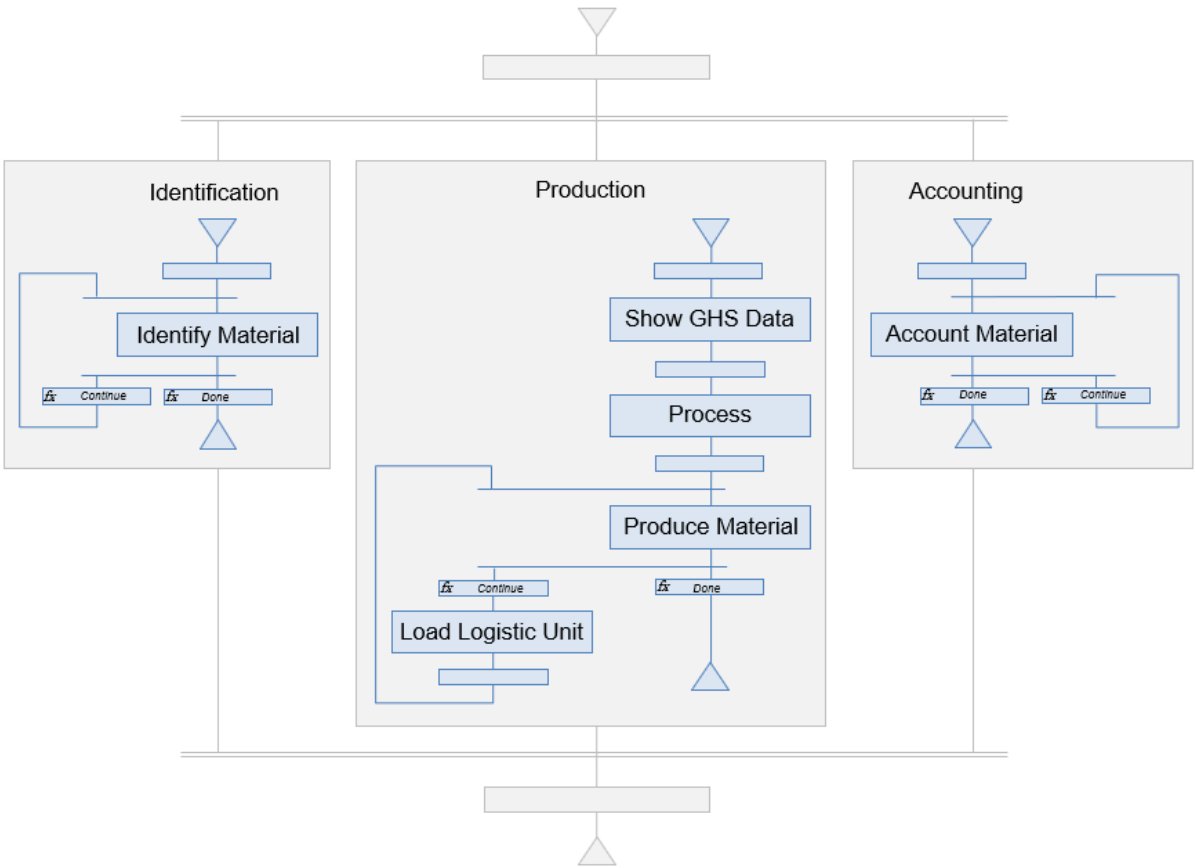


Figure 2: Operation with sequential material tracking

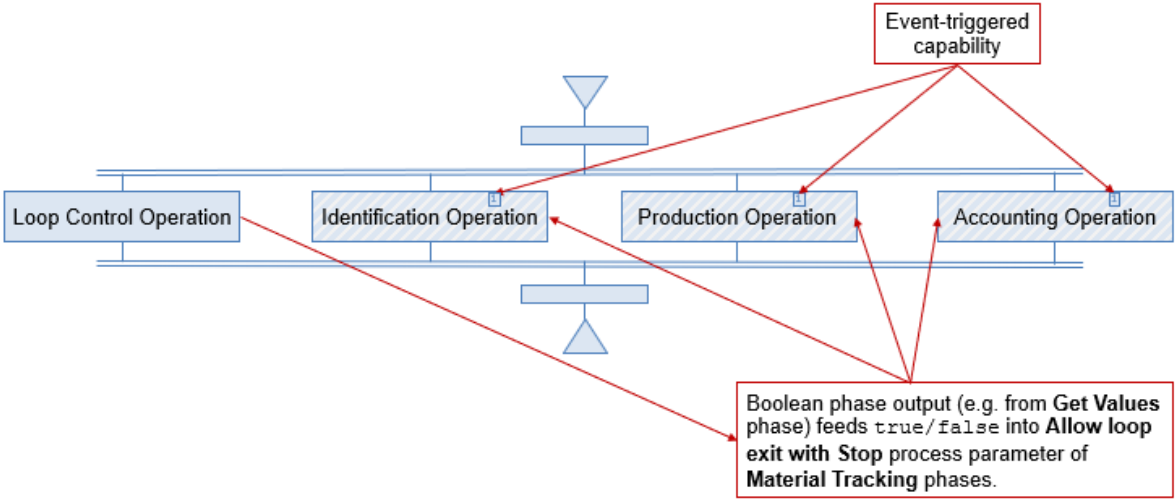


Figure 3: Operation with sequential material tracking

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3 Identify Material Phase (SR0050+)

The **Identify material** phase allows an operator to identify material on subplot and logistic unit level for further processing.

Example use cases are:

- Identify material prior to dispensing
The batch status of the materials must be **Released**. This material-specific requirement can be defined and corresponding violations can be tracked as exceptions.
- Identify material before mixing
Only allocated batches are allowed to be utilized in the mixing process. An allocation check is specified in the phase. Identification of other batches can be tracked as exceptions.
- Unidentify material
Material that has been identified is bound to an order step. As long as none of the previously identified sublots has been accounted, their identification can be revoked. This unbinds the material from the order step and makes it available for identification elsewhere.

Scanned or manually entered batches and sublots or logistic units (and their sublots) are checked against configurable settings

- batch and subplot status
- expiry date
- batch allocation

and built-in settings

- material is MFC-relevant
- subplot is produced for the current order step (only for intra materials)
- sublots are exclusively used by the current order.

The list of identified sublots and logistic units with their quantities and material-related information is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668365](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2668015](#)) (e.g. revoking an identification).


After completion, the phase displays the identified material with the following data in the Execution Window:

- batch and/or subplot identifiers
 - In case a logistic unit has been identified, the phase also displays the logistic unit identifier.

- planned quantity
- identified quantity
- accounted quantity with accounting status (if available).

The Navigator displays the processing result and provides access to the post-completion exceptions.

Identify the materials for tableting.

\$SL00000005BX11 Refresh 

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	10 g		
		BX11 / SL00000005		10 g		
20	D005-04 / Talc		(20.0 g)	0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	0 g		



 Confirm 

Figure 4: Identify material during execution (sequential processing)

Identify the materials for tableting.

Refresh 


Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	20.0 g	10.0 g	Accounted
		BX54 / SL00000058		10.0 g		
		BX53 / SL00000057		10.0 g		
20	D005-04 / Talc		(20.0 g)	100.0 g	20.0 g	Accounted
		BX55 / SL00000059		100.0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105.0 g	1,015.0 g	Accounted
		BX58 / SL00000062		200.0 g		
		BX57 / SL00000061		400.0 g		
		BX56 / SL00000060		505.0 g		

D003-04: Re-identify 10.0 g
D005-04: Re-identify 20.0 g
D130-01: Re-identify 200.0 g

 Confirm 

Figure 5: Identify material during execution (sequential processing)

Identify the product for packaging.

\$SL00000069BX65 Refresh 

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	1,200.0 g	900 g	
		BX65 / SL00000069		300.0 g		



☐ Continue ☒ Done Confirm 

Figure 6: Identify material during execution (sequential processing)

Identify the product for packaging.

\$SL00000071BX69 Refresh 

Pos.	Material	Allocated or identified batch / subplot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	600.0 g		
		BX69 / SL00000071		300.0 g		


☐ Continue ☒ Stop Confirm 

Figure 7: Identify material during execution (sequential processing)

3.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668363](#)), in the Navigator ([GID-2668364](#)), and in the sub-report ([GID-2668365](#)).

3.1.1 Representation during Execution (SR0050.1+)

The representation during execution depends on the phase mode.

3.1.1.1 GID-2669787 PREVIEW MODE (SR0050.1.3)

1. <Instruction text> (taken from **Instruction (SR0050.8.1)** process parameter ([GID-2669800](#)))
2. Box for scanner input (disabled)
3. **Refresh** button (disabled)
4. List of materials available for identification (Table of materials (SR0050.1.2) ([GID-2669789](#))) (taken from material input parameters (SR0050.6.1) ([GID-2669796](#)))
5. Material-related comment to execution (only visible if comment is maintained for the order step input)
6. **Continue** and **Done (Stop)** option buttons (both disabled) The buttons are only visible if the **Loop configuration (SR0050.8.17)** process parameter ([GID-2669801](#)) is not set to **No loop**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0050.8.20)** process parameter ([GID-2669802](#)) is enabled.

7. **Enable** button (disabled). The button is not visible in case a phase completion signature was configured during authoring. The button is only visible if the **Loop configuration (SR0050.8.17)** process parameter [\(GID-2669801\)](#) is set to **No loop**.
8. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.2 GID-2669788 ACTIVE MODE (SR0050.1.1)

1. Instruction table panel and/or instruction link panel (only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
(taken from **Instruction (SR0050.8.1)** process parameter [\(GID-2669800\)](#))
3. Box for scanner input (disabled)
4. **Refresh** button
5. List of materials available for identification (Table of materials (SR0050.1.2) [\(GID-2669789\)](#))
(taken from material input parameters (SR0050.6.1) [\(GID-2669796\)](#))
6. Material-related comment to execution (only visible if comment is maintained for the order step input)
7. **Continue** and **Done (Stop)** option buttons (**Continue** selected) The buttons are only visible if the **Loop configuration (SR0050.8.17)** process parameter [\(GID-2669801\)](#) is not set to **No loop**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0050.8.20)** process parameter [\(GID-2669802\)](#) is enabled.
8. **Enable** button (unlocks the **Confirm** button). The button is not visible in case a phase completion signature was configured during authoring. The button is only visible if the **Loop configuration (SR0050.8.17)** process parameter [\(GID-2669801\)](#) is set to **No loop**.
9. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.3 GID-2669789 TABLE OF MATERIALS (SR0050.1.2)

Data available per batch/sublot:

Content	UI text	Comment
Position	Pos.	<p>Ordered by position, ascending. Taken from material input parameters (SR0050.6.1) process inputs (GID-2669796).</p> <p>On transfer of an alternative material, the position is retained.</p>
Material identifier and short description	Material	<p>Taken from material input parameters (SR0050.6.1) process inputs (GID-2669796).</p>
Logistic unit, batch, or subplot identifier(s)	Allocated or identified logistic unit / batch / subplot	<p>Summary line per position: List of all allocated batches or transferred sublots.</p> <p>Line per subplot: Logistic unit ID of the subplot (only if PharmaSuite is configured to communicate with Warehouse Management and the logistic unit is identified instead of the subplot).</p> <p>After the identification of a transferred subplot, the subplot is removed from the summary line.</p>
Planned quantity and range	Planned quantity [Limits]	<p>(Taken and calculated from material input parameters (SR0050.6.1) process inputs (GID-2669796)).</p> <p>Summary line per position: Display of quantity depends on Planned quantity mode.</p> <p>None - A defined planned quantity is only for information and displayed in brackets.</p> <p>As produced - Shown as N/A as long as the predecessor position has not been closed. After closing the predecessor position, its produced quantity is displayed here. Additionally, the calculated limits are displayed if the defined tolerance is > 0.</p>

Content	UI text	Comment
		As defined - Planned quantity. Additionally, the calculated limits are displayed if the defined tolerance is > 0.
Identified quantity	Identified quantity	Summary line per position: Total of all identified sublots for a position. Line per subplot: Sublot quantity at the time of identification.
Accounted quantity	Accounted quantity	Summary line per position: Total of all accounted sublots for a position. Line per subplot: Accounted subplot quantity. Column is not displayed in case the Auto consume attribute of the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to Yes .
Status of accounting (Set by Account Material (SR0070+) phase (GID-2668022))	Accounting status	Summary line per position only. First row: Initially Empty . Comparison result between planned and accounted quantity (Below tolerance, In tolerance, Above tolerance). Second row: Initially Empty . The last accounting phase instance sets Accounted . Column is not displayed in case the Auto consume attribute of the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to Yes .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.4 GID-2669790 COMPLETED MODE (SR0050.1.4)

1. Instruction table panel and/or instruction link panel (only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text> (taken from **Instruction (SR0050.8.1)** process parameter [\(GID-2669800\)](#))
3. Box for scanner input (disabled)
4. **Refresh** button (disabled)
5. List of materials available for identification (Table of materials (SR0050.1.2) [\(GID-2669789\)](#)) (taken from material input parameters (SR0050.6.1) [\(GID-2669796\)](#))
6. Material-related comment to execution (only visible if comment is maintained for the order step input)
7. **Continue** and **Done (Stop)** option buttons (keep last selection, both disabled) The buttons are only visible if the **Loop configuration (SR0050.8.17)** process parameter [\(GID-2669801\)](#) is not set to **No loop**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0050.8.20)** process parameter [\(GID-2669802\)](#) is enabled.
8. **Enable** button (disabled). The button is not visible in case a phase completion signature was configured during authoring. The button is only visible if the **Loop configuration (SR0050.8.17)** process parameter [\(GID-2669801\)](#) is set to **No loop**.
9. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2 Representation in Navigator (SR0050.4+)

The Navigator provides the following details:

3.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
 - Example:
Identify mixing inputs

3.1.2.2 GID-2669792 INFORMATION COLUMN (SR0050.4.1)

- <Continue, Stop, or Done> representing the content of the **Result (SR0050.9.1)** output variable [\(GID-2668402\)](#).
 - Example: Done

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2.3 GID-2669793 ACTION COLUMN (SR0050.4.2)

- Identify, identify another subplot.
- Undo, revoke identification of a subplot.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.3 Representation in Sub-report (SR0050.5+)

The sub-report contains the following information:

3.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

3.1.3.2 GID-2669795 SUB-REPORT ELEMENTS (SR0050.5.1)

- Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
- Summary line per position with material identifier and short description, planned quantity and identified quantity
- List of identified sublots and logistic units per material position, including batch identifier and identified quantity
- In case the **Loop configuration (SR0050.8.17)** process parameter ([GID-2669801](#)) is configured to loop the phase, the last instance (completed with the **Done** button) displays as summary the list of the sublots for all instances.
- Material-related comment to execution (only visible if comment was visible during execution, i.e. was maintained for the order step input at that time)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2 Business Logic (SR0050.2+)

The phase implements the following business logic.

3.2.1 GID-2668366 Identify material (SR0050.2.1)

Function: Identify pre-defined materials

Trigger: Phase becomes active

Postcondition: Pre-defined materials are identified

Step	#	Description
Phase activation	10	Phase displays its user interface according to the Active mode (SR0050.1.1) layout (GID-2669788) .
Must loop check	15	In case the phase is configured to Must loop after each identification according to the Loop configuration (SR0050.8.17) process parameter (GID-2669801) and there was already a successful identification, the phase ignores all further identifications and needs to be completed first. Phase displays the Loop required (SR0050.3.6.15) error message (GID-2668397) .
Operator scans barcode	20	The Scan material barcode (SR0050.2.2) function (GID-2668367) becomes active.
Scanned barcode belongs to a logistic unit	25	Phase retrieves all sublots that are currently loaded on the identified logistic unit and performs for each subplot the checks listed below. If no subplot is found on the logistic unit, phase displays the No subplot on logistic unit (SR0050.3.6.8) error message (GID-2668390) .
Phase performs fixed checks	30	If one of the following checks is violated, phase displays an error message: <ul style="list-style-type: none"> Identified material must be MFC-relevant, MFC check failed (SR0050.3.6.1) error message (GID-2668383). Sublots must be produced for the current order (only for intra materials), Wrong order (SR0050.3.6.2) error message (GID-2668384). Sublot must not be identified by another order, Sublot already identified (SR0050.3.6.3) error message (GID-2668385). Treatment ID check In the default configuration, the phase skips the check. See also Enable and Configure Treatment ID Support (SR0050.11.1) configuration key (GID-2668403). If the check is enabled and fails, the related Treatment ID check failed (SR0050.3.6.9) error message (GID-2668391) is displayed.

Step	#	Description
Minimum batch status check	40	<p>According to Batch status check configuration (SR0050.8.7) process parameter (GID-2669804), batch status is greater than or equal to the configured minimum batch status.</p> <p>If the check fails, phase creates the Failed batch status check (SR0050.3.2.5) system-triggered exception (GID-2669817).</p>
Batch allocation check	50	<p>According to Allocation check configuration (SR0050.8.9) process parameter (GID-2669806), batch allocation must be met.</p> <p>If the check fails, phase creates the Failed batch allocation check (SR0050.3.2.6) system-triggered exception (GID-2669818).</p>
Expiry date check	60	<p>According to Expiry date check configuration (SR0050.8.8) process parameter (GID-2669805), expiry date must be defined and beyond the current date plus the configured time to expire.</p> <p>If the check fails, phase creates the Failed expiry date check (SR0050.3.2.7) system-triggered exception (GID-2669819).</p>
Sublot status check	65	<p>If the check is enabled according to the Sublot status check configuration (SR0050.8.15) process parameter (GID-2671685), the check is performed.</p> <p>If the identified sublot has no status set, the check always passes.</p> <p>If the identified sublot has a status lower than the configured minimum sublot status, the check fails (Blocked < Quality Inspection < Unrestricted).</p> <p>If the check fails, phase creates the Failed sublot status check (SR0050.3.2.8) system-triggered exception (GID-2669820).</p>
TITR warning and maximum threshold checks	67	<p>If the TITR warning threshold check is enabled according to the TITR warning threshold check process parameter (GID-3296571), the check is performed.</p> <p>If the Duration to threshold attribute of the TITR warning threshold check process parameter (GID-3296571) is defined, all currently active TITR counters are increased for the comparison by this Duration to threshold attribute value.</p> <p>If any of the comparisons (TITR counter (+ Duration to threshold) >= TITR warning threshold) of the identified sublot are true, the phase creates the Failed TITR warning threshold check system-triggered exception (GID-3296573).</p> <p>If the TITR maximum threshold check is enabled according to the TITR maximum threshold check process parameter (GID-3296582), the check is performed.</p>

Step	#	Description
		<p>If the Duration to threshold attribute of the TITR maximum threshold check process parameter (GID-3296582) is defined, all currently active TITR counters are increased for the comparison by this Duration to threshold attribute value.</p> <p>If any of the comparisons (TITR counter (+ Duration to threshold) >= TITR maximum threshold) of the identified subplot are true, the phase creates the Failed TITR maximum threshold check system-triggered exception (GID-3296583).</p> <p>If the maximum threshold is reached for a TITR counter, a violation of the warning threshold for the same TITR counter is suppressed.</p>
	70	In case a logistic unit has been scanned and for one of the sublots of the logistic unit a check fails, no subplot of the logistic unit is identified.
	80	If all checks have passed successfully, material has been identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.2 GID-2668367 Scan material barcode (SR0050.2.2)

- Function: Scan of material barcode
- Trigger: Operator scans barcode
- Postcondition: Material barcode is scanned

Step	#	Description
Operator scans barcode	10	Phase reads scanned data.
	20	<ul style="list-style-type: none"> ▪ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ▪ If barcode reading was technically not successful, phase remains in listening mode. ▪ If barcode reading was not successful, phase displays the Cannot find subplot or logistic unit (SR0050.3.6.4) error message (GID-2668386).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.3 GID-2668368 Unit procedure context (SR0050.2.5)

- Function: Define unit procedure context
- Trigger: Pre-defined materials are identified
- Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that identified materials are only recognized within the given unit procedure.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.4 GID-2668369 Auto consumption (SR0050.2.6)

- Function: Support of automatic consumption
- Trigger: Operator confirms phase
- Postcondition: Consumption of entire subplot quantity is recorded automatically

Step	#	Description
Automatic consumption	10	According to Consumption configuration (SR0050.8.4) process parameter (GID-2669803), phase records the identified subplot as fully consumed and flags the subplot as logically deleted .
	20	Only if PharmaSuite is configured to communicate the consumption with Warehouse Management: In case a warehouse-related error has occurred, phase displays the Warehouse error (SR0050.3.6.6) error message (GID-2668388). The phase can only be completed when the Warehouse error (SR0050.3.1.4) user-triggered exception (GID-2669825) has been recorded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.5 GID-2668370 Phase completion (SR0050.2.7)

- Function: Completion of phase
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase with Done or No loop configuration	10	If the Auto consume attribute of the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to Yes , phase continues with the Auto consumption (SR0050.2.6) function (GID-2668369) .
	20	The Accounting checks (SR0050.2.8) function (GID-2668371) becomes active.
	30	In order to be completed, the phase requires all system-triggered exceptions to be recorded. Only if PharmaSuite is configured to communicate with Warehouse Management and the Warehouse error (SR0050.3.1.4) user-triggered exception (GID-2669825) has not been recorded, phase displays the Missing warehouse exception recording (SR0050.3.6.7) error message (GID-2668389) . The phase can only be completed when the Warehouse error (SR0050.3.1.4) user-triggered exception (GID-2669825) has been recorded.
	40	If all checks have passed successfully and all exceptions have been recorded, the Result (SR0050.9.1) output variable (GID-2668402) is set to DONE. Further steps are skipped.
Operator confirms phase with Continue or Stop	50	If the Auto consume attribute of the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to Yes , phase continues with the Auto consumption (SR0050.2.6) function (GID-2668369) .
	60	The system checks if material was identified for a position that is configured with the As defined planned quantity mode but the consumed quantity exceeds the upper limit of the planned quantity. If the check fails for the first time for a position, phase creates the Quantity out of tolerance (SR0050.3.2.9) system-triggered exception (GID-2669821) .
	70	If all exceptions have been recorded, the Result (SR0050.9.1) output variable (GID-2668402) is set to CONTINUE or STOP, respectively.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.6 GID-2668371 Accounting checks (SR0050.2.8)

- Function: Accounting checks at completion of phase
- Trigger: Operator confirms phase with **Done** or **No loop** configuration
- Postcondition: Accounting checks are completed

Step	#	Description
Check if predecessor is closed	10	In case a position is configured with the planned quantity mode As produced and the planned quantity is not set yet (the predecessor position is not completed), phase displays the Predecessor position not completed (SR0050.3.6.12) error message (GID-2668394).
Check transferred sublots	20	In case for a position that is configured with the planned quantity mode As produced not all produced sublots of the predecessor have been identified, phase displays the Not all transferred sublots identified (SR0050.3.6.11) error message (GID-2668393).
Check mandatory positions	30	<p>If the Auto consume attribute of the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to Yes:</p> <ul style="list-style-type: none"> ▪ If for any position that is configured with the planned quantity modes As defined or As produced nothing is identified, phase displays the Auto-Consume and missing material identification (SR0050.3.6.13) error message (GID-2668395). ▪ The system checks if material was identified for a position that is configured with the planned quantity modes As defined but the consumed quantity is not within the limits of the planned quantity. If the check fails, phase creates the Quantity out of tolerance (SR0050.3.2.9) system-triggered exception (GID-2669821). <p>If the Auto consume attribute of the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to No:</p> <ul style="list-style-type: none"> ▪ In case the accounting status of any position that is configured with the planned quantity modes As defined or As produced is not Accounted, phase displays the Accounting check failed (SR0050.3.6.10) error message (GID-2668392).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3 Recipe Parameters

The phase provides material input parameters as process inputs ([GID-2668372](#)) and process parameters ([GID-2668373](#)).

3.3.1 Process Inputs (SR0050.6+)

3.3.1.1 GID-2669796 MATERIAL INPUT PARAMETERS (SR0050.6.1)

The default material input parameters are available to define which materials can be identified during execution.

Quantity definitions of the material input parameters are populated to the **Table of materials (SR0050.1.2)** list ([GID-2669789](#)) that is displayed during execution. This includes the reflection of quantity-related calculations during order explosion.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2 Process Parameters (SR0050.8+)

The following process parameters define the behavior of the phase.

3.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

3.3.2.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns . Default setting: 1 column .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

3.3.2.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

3.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

3.3.2.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the Instruction link definition process parameter (GID-2669799) . Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

3.3.2.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the Link URL attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.

Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

3.3.2.3 BASIC PARAMETERS

3.3.2.3.1 GID-2669800 INSTRUCTION (SR0050.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. Restriction: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.4 PROCESSING PARAMETERS

3.3.2.4.1 GID-2669801 LOOP CONFIGURATION (SR0050.8.17)

Attribute	Type	Comment
Loop configuration	Choice list	Defines if the phase shall use a loop or static mode. Available settings: No loop , Can loop , Must loop . Default setting: No loop .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.4.2 GID-2669802 ALLOW LOOP EXIT WITH STOP (SR0050.8.20)

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the Done button is replaced with a Stop button. This allows a loop exit with the same behavior as the Continue button. Default setting: No .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.4.3 GID-2669803 CONSUMPTION CONFIGURATION (SR0050.8.4)

Attribute	Type	Comment
Auto consume	Flag	Controls if the identified subplot is registered as fully consumed when the phase is completed with the Confirm button. If you have more than one phase sharing the same material within one operation, all sublots will be consumed even if the flag is set only for one of the phases.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

3.3.2.5.1 GID-2669804 BATCH STATUS CHECK CONFIGURATION (SR0050.8.7)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum batch status attribute of the Batch check definition (SR0050.8.3) process parameter (GID-2669807) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed batch status check (SR0050.3.2.5)** system-triggered exception [\(GID-2669817\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.2 GID-2669805 EXPIRY DATE CHECK CONFIGURATION (SR0050.8.8)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum time to expire attribute of the Batch check definition (SR0050.8.3) process parameter (GID-2669807) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed expiry date check (SR0050.3.2.7)** system-triggered exception [\(GID-2669819\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.3 GID-2669806 ALLOCATION CHECK CONFIGURATION (SR0050.8.9)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, the check is only performed if there are allocation requirements.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed batch allocation check (SR0050.3.2.6)** system-triggered exception ([GID-2669818](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.4 GID-2669807 BATCH CHECK DEFINITION (SR0050.8.3)

Attribute	Type	Comment
Minimum batch status	Choice list	Defines the minimum batch status required for material identification. Default setting: Released .
Minimum time to expire	Numeric	Defines the number of days allowed between the actual identification date and expiry date.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.5 GID-2669808 SUBLOT STATUS CHECK CONFIGURATION (SR0050.8.15)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum subplot status attribute of the Sublot check definition (SR0050.8.16) process parameter (GID-2669809) is set. Default setting: False
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Failed subplot status check (SR0050.3.2.8)** system-triggered exception [\(GID-2669820\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.6 GID-2669809 SUBLOT CHECK DEFINITION (SR0050.8.16)

Attribute	Type	Comment
Minimum subplot status	Choice list	Defines the minimum subplot status required for material identification. Available settings: Blocked , Quality Inspection , Unrestricted . Default setting: Unrestricted .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.7 GID-2669810 QUANTITY OUT OF TOLERANCE (SR0050.8.18)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Quantity out of tolerance (SR0050.3.2.9)** system-triggered exception ([GID-2669821](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.8 GID-3296571 TITR WARNING THRESHOLD CHECK

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that no TITR warning threshold is reached. Default setting: False .
Duration to threshold	Duration	Defines the shortest allowed time interval between a currently active TITR counter and its warning threshold. Default setting: Not defined .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment) . Default setting: High , defined by the DefaultRiskClassForPhaseProcessParameter configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Time in temperature range warning threshold check** system-triggered exception [\(GID-3296573\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.5.9 GID-3296582 TITR MAXIMUM THRESHOLD CHECK

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that no TITR maximum threshold is reached. Default setting: False .
Duration to threshold	Duration	Defines the shortest allowed time interval between a currently active TITR counter and its maximum threshold. Default setting: Not defined .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment) . Default setting: High , defined by the DefaultRiskClassForPhaseProcessParameter configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Time in temperature range maximum threshold check** system-triggered exception [\(GID-3296583\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.6 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

3.3.2.6.1 GID-2669811 IDENTIFY MANUALLY (SR0050.8.10)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Identify manually (SR0050.3.1.1)** user-triggered exception ([GID-2669823](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.6.2 GID-2669812 UNDO IDENTIFICATION (SR0050.8.11)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Undo identification (SR0050.3.1.2)** user-triggered exception ([GID-2669824](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.6.3 GID-2669813 WAREHOUSE ERROR (SR0050.8.14)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.

See also **Warehouse error (SR0050.3.1.4)** user-triggered exception ([GID-2669825](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.6.4 GID-2669814 FORCE COMPLETION (SR0050.8.19)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Force completion (SR0050.3.1.5)** user-triggered exception ([GID-2669827](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.7 CONFIGURATION OF POST-COMPLETION EXCEPTIONS

3.3.2.7.1 GID-2669815 POST - IDENTIFY ADDITIONALLY (SR0050.8.12)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Identify additionally (SR0050.3.3.1)** post-completion exception ([GID-2669829](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2.7.2 GID-2669816 POST - UNDO IDENTIFICATION (SR0050.8.13)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Undo identification (SR0050.3.3.2)** post-completion exception ([GID-2669830](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.4 Exceptions (SR0050.3+)

The phase supports user-defined, user-triggered ([GID-2668381](#)), system-triggered ([GID-2668380](#)), and post-completion exceptions ([GID-2668382](#)) and their configuration by means of process parameters ([GID-2668373](#)).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

3.4.1 System-triggered Exceptions (SR0050.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

3.4.1.1 GID-2669817 FAILED BATCH STATUS CHECK (SR0050.3.2.5)

Representation of the exception:

- <Exception text>
(taken from **Batch status check configuration (SR0050.8.7)** process parameter [\(GID-2669804\)](#))
Batch: <batch identifier>,
Expected value: <status>
Actual value: <status>
- Example:
The current status of the batch is not appropriate.
Batch: BX127
Expected value: Released
Actual value: Quarantined

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.2 GID-2669818 FAILED BATCH ALLOCATION CHECK (SR0050.3.2.6)

Representation during exception handling:

- <Exception text>
(taken from **Allocation check configuration (SR0050.8.9)** process parameter [\(GID-2669806\)](#))
Batch: <batch identifier>
- Example:
The current batch has not been allocated.
Batch: BX127

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.3 GID-2669819 FAILED EXPIRY DATE CHECK (SR0050.3.2.7)

Representation of the exception:

- <Exception text>
(taken from **Expiry date check configuration (SR0050.8.8)** process parameter [\(GID-2669805\)](#))
Batch: <batch identifier>
Expected value: <number of days>
Actual value: <date>

- Example:
The current expiry date is not sufficient anymore.
Batch: BX127
Expected value: 720 days
Actual value: 10/12/2011

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.4 GID-2669820 FAILED SUBLOT STATUS CHECK (SR0050.3.2.8)

If the check is enabled according to the **Sublot status check configuration (SR0050.8.15)** process parameter ([GID-2669808](#)), the check is performed. If the identified subplot has no status set, the check always passes. If the identified subplot has a status lower than the configured minimum subplot status, the check raises the exception (**Blocked** < **Quality Inspection** < **Unrestricted**).

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

- <Exception text>
(taken from **Sublot status check configuration (SR0050.8.15)** process parameter ([GID-2669808](#)))
Batch: <batch identifier>, material: <material identifier>, subplot: <subplot identifier>
Expected value: <subplot status>
Actual value: <subplot status>
- Example:
Sublot status check failed.
Batch: BX123, material: D130-01, subplot: SL00001234
Expected value: Unrestricted
Actual value: Quality Inspection

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.5 GID-3296573 FAILED TITR WARNING THRESHOLD CHECK

Representation of the exception:

- <Exception text>
(taken from **TITR warning threshold check** process parameter ([GID-3296571](#)))
Batch: <batch identifier>, material: <material identifier>, subplot: <subplot identifier>
Temperature range: [<min. temperature> .. <max. temperature>], warning: <warning threshold>, current value: <current TITR counter value>

(...)

Temperature range: [<min. temperature> .. <max. temperature>], warning: <warning threshold>, current value: <current TITR counter value>

▪ Example:

A TITR counter has reached the warning limit.

Batch: BX123, material: D130-01, subplot: SL00001234

Temperature range: [15°C .. 25°C], warning: 4d, current value: 4d 3h

Temperature range: [-10°C .. 0°C], warning: 20d, current value: 21d 5min

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.4.1.6 GID-3296583 FAILED TITR MAXIMUM THRESHOLD CHECK

Representation of the exception:

▪ <Exception text>

(taken from **TITR maximum threshold check** process parameter ([GID-3296582](#)))

Batch: <batch identifier>, material: <material identifier>, subplot: <subplot identifier>

Temperature range: [<min. temperature> .. <max. temperature>], maximum: <maximum threshold>, current value: <current TITR counter value>

(...)

Temperature range: [<min. temperature> .. <max. temperature>], maximum: <maximum threshold>, current value: <current TITR counter value>

▪ Example:

A TITR counter has reached the maximum limit.

Batch: BX123, material: D130-01, subplot: SL00001234

Temperature range: [15°C .. 25°C], maximum: 4d, current value: 4d 3h

Temperature range: [-10°C .. 0°C], maximum: 20d, current value: 21d 5min

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.4.1.7 GID-2669821 QUANTITY OUT OF TOLERANCE (SR0050.3.2.9)

If the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter ([GID-2669803](#)) is set to **Yes**, the planned quantity mode of any material position assigned to the phase is **As defined**, and the identified quantity is not within the range of the planned quantity and its tolerance, an exception is raised.

Representation of the exception:

- <Exception text>
(taken from **Quantity out of tolerance (SR0050.8.18)** process parameter [\(GID-2669810\)](#))
The following positions are out of tolerance:
Material: <material identifier>, Planned quantity: <planned quantity [lower limit .. upper limit]>,
Identified quantity: <identified quantity>
- Example:
Wrong amount of material identified.
The following positions are out of tolerance:
Material: D130-01, Planned quantity: 100.0 kg [99.0 kg .. 105.0 kg], Identified quantity:
50.000 kg

TIP

If the upper limit of the planned quantity of the material position is exceeded, the exception is triggered only at the first occurrence, since the excess cannot be reversed in further identification loops.
Contrary to this, if the lower limit is violated, an exception is raised only if the identification was completed with DONE.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.8 GID-2669822 MULTIPLE EXCEPTIONS (SR0050.3.2.3)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

In case a logistic unit has been identified, the combined exception contains information about all exceptions of all sublots of the logistic unit and displays the identifier of the logistic unit. In this case, the highest risk is calculated from all related exceptions of all sublots.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2 User-triggered Exceptions (SR0050.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

3.4.2.1 GID-2669823 IDENTIFY MANUALLY (SR0050.3.1.1)

The **Identify manually** exception allows an operator to identify material manually as long as the material position is not accounted with a planned quantity mode **As produced** or **As defined**.

Representation during exception handling:

- Instruction:
 - PharmaSuite is not configured to communicate with Warehouse Management:
To identify manually, enter the subplot identifier.
Box for barcode input.
Confirm button.
 - PharmaSuite is configured to communicate with Warehouse Management:
To identify manually, enter the subplot or logistic unit identifier.
Box for barcode input.
Confirm button.
- Exception text:
<Exception text>
(taken from **Identify manually (SR0050.8.10)** process parameter [\(GID-2669811\)](#))
 - Identified subplot: <subplot identifier>
 - Identified logistic unit: <logistic unit identifier>
 - Example:
Manual identification
Identified subplot or logistic unit: SL00005678

Step	#	Description
Operator confirms exception	10	Phase executes the checks of steps 15 and 25 to 70 of the Identify material (SR0050.2.1) function (GID-2668366) .
	20	If all checks have passed successfully, phase records the exception according to Identify manually (SR0050.8.10) process parameter (GID-2669811) .
	30	Material is identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.2 GID-2669824 UNDO IDENTIFICATION (SR0050.3.1.2)

The **Undo identification** exception allows an operator to revoke the identification of a subplot as long as the subplot has not been accounted and the material position is not accounted with a planned quantity mode **As produced** or **As defined**.

In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit and that have not been accounted is revoked.

Representation during exception handling:

- Instruction:
 - PharmaSuite is not configured to communicate with Warehouse Management:
To undo the identification, enter the identifier of the affected subplot.
Box for barcode input.
Confirm button.
 - PharmaSuite is configured to communicate with Warehouse Management:
To undo the identification, enter the identifier of the affected subplot or logistic unit.
Box for barcode input.
Confirm button.
- Exception text:
<Exception text>
(taken from **Undo identification (SR0050.8.11)** process parameter [\(GID-2669812\)](#))
 - Unidentified subplot: <subplot identifier>; Quantity: <subplot quantity>
 - Unidentified logistic unit: <logistic unit identifier>
 - Example:
Undo identification
Unidentified subplot: SL00005678; Quantity: 500 kg

Step	#	Description
Operator confirms exception	10	If the subplot has not been accounted, phase records the exception according to Undo identification (SR0050.8.11) process parameter (GID-2669812) . In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit and that have not been accounted is revoked. Otherwise phase displays the Cannot revoke identification (SR0050.3.6.5) error message (GID-2668387) .
	20	Sublot(s) are no longer identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.3 GID-2669825 WAREHOUSE ERROR (SR0050.3.1.4)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- **Warehouse error (SR0050.3.6.6)** error message ([GID-2668388](#))

Representation of the exception:

- Instruction:
Confirm to record the warehouse error.
Confirm button.
- <Exception text>
(taken from **Warehouse error (SR0050.8.14)** process parameter ([GID-2669813](#)))
A warehouse error has occurred while consuming material.
<Error message from the warehouse system>
- Example:
Document warehouse error
A warehouse error has occurred while consuming material.
<Error message from the warehouse system>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.4 GID-2669826 WAREHOUSE ERROR - LOGIC (SR0050.3.1.4.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the Warehouse error (SR0050.8.14) process parameter (GID-2669813).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.5 GID-2669827 FORCE COMPLETION (SR0050.3.1.5)

The **Force completion** exception allows an operator to complete the phase even if one or several of following errors prevent to complete the phase:

- **Accounting check failed (SR0050.3.6.10)** error message ([GID-2668392](#))
- **Not all transferred sublots identified (SR0050.3.6.11)** error message ([GID-2668393](#))
- **Predecessor position not completed (SR0050.3.6.12)** error message ([GID-2668394](#))
- **Auto-consume and missing material identification (SR0050.3.6.13)** error message ([GID-2668395](#))
- The planned quantity is 0 and the planned quantity mode is **As produced** (predecessor is closed with 0 quantity) or **As defined** (no **Planned quantity** defined with material parameter).

Representation of the exception:

- Instruction:
Force the completion.
Confirm button.
- <Exception text>
(taken from **Force completion (SR0050.8.19)** process parameter ([GID-2669814](#)))
Force the completion of the phase in spite of the following errors:
<error messages that would appear at phase completion>
 - Example:
Finish the phase manually.
Force the completion of the phase in spite of the following errors:
Not all materials have been identified.
Not all materials have been accounted.
At least one predecessor of an As Produced position has not been processed yet.

Step	#	Description
Phase checks if the exception is required	10	<p>If none of the following errors would prevent the normal completion of the phase:</p> <ul style="list-style-type: none"> ▪ Accounting check failed (SR0050.3.6.10) error message (GID-2668392) ▪ Not all transferred sublots identified (SR0050.3.6.11) error message (GID-2668393) ▪ Predecessor position not completed (SR0050.3.6.12) error message (GID-2668394) ▪ Auto-consume and missing material identification (SR0050.3.6.13) error message (GID-2668395) <p>phase aborts the exception with the Force completion not required (SR0050.3.6.14) error message (GID-2668396).</p>

Step	#	Description
Operator confirms exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.6 GID-2669828 MULTIPLE EXCEPTIONS (SR0050.3.1.3)

In case an **Identify manually** (SR0050.3.1.1) user-triggered exception ([GID-2669823](#)) coincides with system-triggered exceptions ([GID-2668380](#)), only one combined exception (user-triggered exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

In case a logistic unit has been identified, the combined exception contains information about all exceptions of all sublots of the logistic unit and displays the identifier of the logistic unit. In this case, the highest risk is calculated from all related exceptions of all sublots.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.3 Post-completion Exceptions (SR0050.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

3.4.3.1 GID-2669829 IDENTIFY ADDITIONALLY (SR0050.3.3.1)

The **Identify additionally** exception allows an operator to manually identify an additional subplot or logistic unit from the Navigator after the completion of the phase. In case the phase is configured to run in the loop mode, the post-completion exception is only available for the last completed phase instance.

Representation of the exception:

- Instruction:
 - PharmaSuite is not configured to communicate with Warehouse Management:
To identify an additional subplot, enter the subplot identifier.
Box for barcode input.
Confirm button.

- PharmaSuite is configured to communicate with Warehouse Management:
To identify an additional subplot or logistic unit, enter its identifier.
Box for barcode input.
Confirm button.
- <Exception text>
(taken from **Post - Identify additionally (SR0050.8.12)** process parameter [\(GID-2669815\)](#))
 - Additionally identified subplot: <subplot identifier>
 - Additionally identified logistic unit: <logistic unit identifier>
 - Example:
Post additional identification
Additionally identified subplot: SL00005678

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator enters barcode.
	30	Phase executes the checks of step 25 to 70 of the Identify material (SR0050.2.1) function (GID-2668366) .
	40	If all checks have passed successfully, phase records the exception according to Post - Identify additionally (SR0050.8.12) process parameter (GID-2669815) .
	45	Only if the Consumption configuration (SR0050.8.4) process parameter (GID-2669803) is set to Yes: <ul style="list-style-type: none"> ▪ Phase records the identified subplot as fully consumed and flags the subplot as logically deleted. ▪ Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred, phase displays the Warehouse error (SR0050.3.6.6) error message (GID-2668388). The Warehouse error (SR0050.3.1.4) user-triggered exception (GID-2669825) is automatically recorded.
	50	Material is identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.3.2 GID-2669830 UNDO IDENTIFICATION (SR0050.3.3.2)

The **Undo identification** exception allows an operator to revoke the identification of a subplot as long as the subplot has not been accounted from the Navigator after the completion of the phase. In case the phase is configured to run in the loop mode, the post-completion exception is only available for the last completed phase instance.

In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit within the current phase instance and that have not been accounted is revoked.

Representation during exception handling:

- Instruction:
- PharmaSuite is not configured to communicate with Warehouse Management:
To undo the identification, enter the identifier of the affected subplot.
Box for barcode input.
Confirm button.
- PharmaSuite is configured to communicate with Warehouse Management:
To undo the identification, enter the identifier of the affected subplot or logistic unit.
Box for barcode input.
Confirm button.
- Exception text:
<Exception text>
(taken from **Post - Undo identification (SR0050.8.13)** process parameter [\(GID-2669816\)](#))
- Unidentified subplot: <subplot identifier>; Quantity: <subplot quantity>
- Unidentified logistic unit: <logistic unit identifier>
- Example:
Undo identification
Unidentified subplot: SL00005678; Quantity: 500 kg

Step	#	Description
Operator triggers action	10	If the subplot has not been accounted, phase records the exception according to Post - Undo identification (SR0050.8.13) process parameter (GID-2669816) . In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit and that have not been accounted is revoked. Otherwise phase displays the Cannot revoke identification (SR0050.3.6.5) error message (GID-2668387) .
	20	Sublot(s) are no longer identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.3.3 GID-2669831 MULTIPLE EXCEPTIONS (SR0050.3.3.3)

In case an **Identify additionally (SR0050.3.3.1)** post-completion exception ([GID-2669829](#)) coincides with system-triggered exceptions ([GID-2668380](#)), only one combined exception (post-completion exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

In case a logistic unit has been identified, the combined exception contains information about all exceptions of all sublots of the logistic unit and displays the identifier of the logistic unit. In this case, the highest risk is calculated from all related exceptions of all sublots.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.5 Information Messages

There are no information messages available.

3.6 Questions

There are no questions available.

3.7 Decisions

There are no decisions available.

3.8 Error Messages (SR0050.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

3.8.1 GID-2668383 MFC check failed (SR0050.3.6.1)

UI text	Comment
Cannot identify the material, since it has already been processed and completed or does not correspond to the required material input. Select a suitable material input, if available.	<p>Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotIdentifySublotMaterial</p> <p>Potential error cause: The identified material is not MFC-relevant for this order. It cannot be used at this point.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.2 GID-2668384 Wrong order (SR0050.3.6.2)

UI text	Comment
The subplot (<subplot ID>) has not been produced for this order step. Select another subplot.	<p>Message pack: srv_inventory.checks Message ID: CheckMaterialForIntermediateOSI_0</p> <p>Potential error cause: The identified material (intra material subplot) has not been produced for the current order. It cannot be used at this point.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.3 GID-2668385 Sublot already identified (SR0050.3.6.3)

UI text	Comment
Cannot identify the subplot (<subplot ID>), since it has already been identified for another order step. Select another subplot.	<p>Message pack: srv_inventory.checks Message ID: CheckSublotBlockedByProcessing_0</p> <p>Potential error cause: The identified material has already been identified for another order. It cannot be used at this point.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.4 GID-2668386 Cannot find subplot or logistic unit (SR0050.3.6.4)

UI text	Comment
Cannot find the subplot or logistic unit in the inventory. Scanned barcode: <identifier> Please check your data.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: BarcodeNotExistTxt

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.5 GID-2668387 Cannot revoke identification (SR0050.3.6.5)

UI text	Comment
Cannot unidentify the <identifier> subplot, since it has already been consumed.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: SublotsConsumedTxt
Cannot unidentify the <identifier> subplot, since it was not identified by the current phase.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: SublotNotFound
Cannot unidentify the <identifier> logistic unit, since none of its sublots have been identified by the current phase.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUUndolIdentNoSublotsTxt
Cannot unidentify the <identifier> logistic unit, since all identified sublots have already been consumed.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUUndolIdentAllSublotsConsumedTxt
An internal error has occurred. Cannot unidentify the <identifier> logistic unit.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUUndolIdentSublotsNotIdentifiedTxt

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.6 GID-2668388 Warehouse error (SR0050.3.6.6)

UI text	Comment
A warehouse error has occurred while consuming material. <Error message from the warehouse system>	Message pack: PhaseProductIdentifyMaterial<version> Message ID: ConsumeSublotWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.7 GID-2668389 Missing warehouse exception recording (SR0050.3.6.7)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: PhaseProductMaterial<version> Message ID: SignWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.8 GID-2668390 No subplot on logistic unit (SR0050.3.6.8)

UI text	Comment
No sublots on logistic unit with <barcode> barcode found.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUIIdentNoSublotsTxt

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.9 GID-2668391 Treatment ID check failed (SR0050.3.6.9)

UI text	Comment
Cannot identify the batch <identifier>. The treatment ID <identifier> of the batch does not match the treatment ID <identifier> of the order.	Message pack: srv_inventory.checks Message ID: CheckTreatmentID_1
Cannot identify the batch <identifier> with the treatment ID <identifier>. The current order has no treatment ID.	Message pack: srv_inventory.checks Message ID: CheckTreatmentID_0
Cannot identify any material. The current order has no treatment ID.	Message pack: srv_inventory.checks Message ID: CheckTreatmentID_2

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.10 GID-2668392 Accounting check failed (SR0050.3.6.10)

UI text	Comment
Cannot confirm the phase, since not all materials have been accounted.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteMatIdentPositionStillOpen_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.11 GID-2668393 Not all transferred sublots identified (SR0050.3.6.11)

UI text	Comment
Cannot confirm the phase, since not all sublots have been identified: <list of not identified sublot identifiers produced at previous step>.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteSublotsToIdentify_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.12 GID-2668394 Predecessor position not completed (SR0050.3.6.12)

UI text	Comment
Cannot confirm the phase, since at least one predecessor of an As Produced position is still open.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteAsProducedPredecessorStillOpen_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.13 GID-2668395 Auto-consume and missing material identification (SR0050.3.6.13)

UI text	Comment
Cannot confirm the phase, since not for all required positions material has been identified.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteNotAllMaterialIdentified_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.14 GID-2668396 Force completion not required (SR0050.3.6.14)

UI text	Comment
There are no errors. Please confirm the phase without exception.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: NoErrorsToBeForced_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.15 GID-2668397 Loop required (SR0050.3.6.15)

UI text	Comment
Cannot identify the material in the current phase run. Confirm the phase and identify in a further run.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: MustLoopAfterIdentification_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9 Output Variables (SR0050.9+)

The following output variables are available to reference the phase's output.

3.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

3.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

3.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

3.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

3.9.5 GID-2668402 Result (SR0050.9.1)

- Data type: String
- Values: CONTINUE, STOP, DONE
- Usage: The output variable provides the result of the phase processing:
- The value is CONTINUE if the phase was completed with **Continue**.
- The value is STOP if the phase was completed with **Stop**.
- The value is DONE if the phase was completed with **Done** or the **Loop configuration (SR0050.8.17)** process parameter ([GID-2669801](#)) is set to **No loop**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.10 Configuration Keys (SR0050.11+)

The following configuration keys are available to configure the phase's behavior.

3.10.1 GID-2668403 Enable and Configure Treatment ID Support (SR0050.11.1)

- **Phase/TreatmentIDSupport**
- **Type:** String
- **Value:** Off
- **Description:** The configuration applies to material identification with the **D Identify material** phase and the **Identify material** phase and to workflow creation with the **Create workflow** phase.
If the value is set to **Off**, no treatment ID is checked during material identification and a created workflow does not inherit the treatment ID of the order.
If the value is set to **TreatmentIDMandatory**, all orders need to have a treatment ID set. If the identified batch has a treatment ID, it must be equal to the order's treatment ID.
If the value is set to **TreatmentIDOptional**, an order does not have to have a treatment ID set. If the identified batch has a treatment ID, it has to be equal to the order's treatment ID.
- **Evaluated:** At subplot or batch identification and at workflow creation.
- **Range:** [Off, TreatmentIDMandatory, TreatmentIDOptional]

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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- FT PharmaSuite® 11.01.00 - Functional Requirement Specification Material Tracking Phases
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4 Account Material Phase (SR0070+)

The **Account material** phase allows an operator to account identified sublots in terms of consumed, wasted, sampled, and returned quantities.

Example use cases are:

- Consume partial sublots
For sublots that were not completely used up during processing, the actual amount of material that has been utilized can be declared as consumed and the remainder can be declared as to be returned.
- Consume sublots completely
If several sublots of one material have been identified and consumed completely, the consumption can be declared per material at once.
- Account samples
A processing step requires to create samples. The quantity that was used for sampling purposes can be declared separately.
- Account unused sublots
One of the identified sublots was not used at all during processing. The entire subplot can be returned.

The number of accounted sublots and their material identifiers are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668406](#)).



Depending on the configured planned quantity mode of an order step input position, the accounted quantity is compared with the planned quantity and its limits. In case of a limit violation an exception is recorded.

After completion the phase displays the accounted material with the following data in the Execution Window:

- batch and/or subplot identifiers
- identified quantity
- consumed quantity
- wasted quantity
- sampled quantity
- returned quantity
- accounting status.

The Navigator displays the processing result.

Account the tableted materials.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted	Sampled	Returned	Status
10	D003-04 / Ethanol 96 %		(10.0 g)	10.0 g	10.0 g	0 g	0 g	0.0 g	
		BX429							
		SL00000042		10.0 g	10.0 g	0 g	0 g	0.0 g	
20	D005-04 / Talc		(20.0 g)	100 g					
		BX430							
		SL00000043		100 g					
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105 g					
		BX432							
		SL00000045		400 g					
		BX433							
		SL00000046		200 g					
		BX434							
		SL00000047		505 g					





 Confirm 

Figure 8: Account material during execution (sequential processing)

Account the packaged material.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted	Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	900 g	580 g	0 g	20 g	0 g	
		BX591							
		SL00000083		300 g					
		SL00000084		300 g	290 g	0 g	10 g	0 g	
		SL00000085		300 g	290 g	0 g	10 g	0 g	




☒ Continue ☐ Done Confirm 

Figure 9: Account material during execution (sequential processing)

Account the packaged material.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted	Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	500 g	500 g	0 g	0 g	0 g	
		BX597							
		SL00000088		500 g	500 g	0 g	0 g	0 g	


☒ Continue (*) ☐ Done Confirm 

Figure 10: Account material during execution (sequential processing)

Account the packaged material.

Refresh  Account 

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted	Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	600 g	300 g	0 g	0 g	0 g	
		BX599							
		SL00000090		300 g	300 g	0 g	0 g	0 g	
		SL00000091		300 g					

☐ Continue ☒ Stop Confirm 

Figure 11: Account material during execution (sequential processing)

4.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668404](#)), in the Navigator ([GID-2668405](#)), and in the sub-report ([GID-2668406](#)).

4.1.1 Representation during Execution (SR0070.1+)

The representation during execution depends on the phase mode.

4.1.1.1 GID-2669832 PREVIEW MODE (SR0070.1.4)

- <Instruction text>
(taken from Instruction (SR0070.8.1) process parameter ([GID-2671969](#)))
- Refresh** button (disabled).
- Account** button (disabled).
- List of materials available for accounting (Table of materials (SR0070.1.2) ([GID-2669834](#)))
(taken from material input parameters (SR0070.6.1) ([GID-2669844](#)))
- Continue** and **Done (Stop)** option buttons (both disabled)
The buttons are only visible in case the **Enable loop** (SR0070.8.6) process parameter ([GID-2671972](#)) is set to **Yes**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop** (SR0070.8.8) process parameter ([GID-2671973](#)) is enabled.
- Enable** button (disabled).
The button is not visible in case a phase completion signature was configured during authoring.
The button is only visible in case the **Enable loop** (SR0070.8.6) process parameter ([GID-2671972](#)) is set to **No**.
- Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.2 GID-2669833 ACTIVE MODE (SR0070.1.1)

1. Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
(taken from Instruction (SR0070.8.1) process parameter [\(GID-2671969\)](#))
3. **Refresh** button.
4. **Account** button.
5. List of materials available for accounting (Table of materials (SR0070.1.2) [\(GID-2669834\)](#))
(taken from material input parameters (SR0070.6.1) [\(GID-2669844\)](#))
6. **Continue** and **Done (Stop)** option buttons (**Continue** selected)
The buttons are only visible in case the **Enable loop (SR0070.8.6)** process parameter [\(GID-2671972\)](#) is set to **Yes**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0070.8.8)** process parameter [\(GID-2671973\)](#) is enabled.
The **Continue** button is marked with "(*)" as soon material is accounted with the current phase instance.
7. **Enable** button (unlocks the **Confirm** button).
The button is not visible in case a phase completion signature was configured during authoring.
The button is only visible in case the **Enable loop (SR0070.8.6)** process parameter [\(GID-2671972\)](#) is set to **No**.
8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.3 GID-2669834 TABLE OF MATERIALS (SR0070.1.2)

Data available per batch/sublot:

Content	UI text	Comment
Position	Pos.	Ordered by position, ascending. Taken from material input parameters (SR0070.6.1) process inputs (GID-2669844) .
Material identifier and short description	Material	Taken from material input parameters (SR0070.6.1) process inputs (GID-2669844) .

Content	UI text	Comment
Identified batch/sublot identifier(s)	Batch ID Sublot ID	Summary line per position: empty Line per batch: Batch identifier Line per sublot: Sublot identifier
Planned quantity and range	Planned quantity [Limits]	<p>Taken from material input parameters (SR0070.6.1) process inputs (GID-2669844).</p> <p>Summary line per position: Display of quantity depends on Planned quantity mode.</p> <p>None - A defined planned quantity is only for information and displayed in brackets.</p> <p>As produced - Shown as N/A as long as the predecessor position has not been closed. After closing the predecessor position, its produced quantity is displayed here. Additionally, the calculated limits are displayed if the defined tolerance is > 0.</p> <p>As defined - Planned quantity. Additionally, the calculated limits are displayed if the defined tolerance is > 0.</p>
Identified quantity	Identified	<p>Summary line per position: Total of all identified sublots for a position.</p> <p>Line per batch: empty</p> <p>Line per sublot: Sublot quantity at the time of identification.</p>
Consumed quantity	Consumed	<p>Summary line per position: Total of all accounted sublots for a position.</p> <p>Line per batch: empty</p> <p>Line per sublot: Consumed quantity as accounted.</p>

Content	UI text	Comment
Wasted quantity	Wasted	Summary line per position: Total of all accounted sublots for a position. Line per batch: empty Line per subplot: Wasted quantity as accounted.
Sampled quantity	Sampled	Summary line per position: Total of all accounted sublots for a position. Line per batch: empty Line per subplot: Sampled quantity as accounted
Returned quantity	Returned	Summary line per position: Total of all accounted sublots for a position. Line per batch: empty Line per subplot: Returned quantity as accounted.
Accounting status	Status	Summary line per position only. First row: Initially Empty . Comparison result between planned and accounted quantity (Below tolerance, In tolerance, Above tolerance). Second row: Initially Empty . A completed phase with result = Done sets Accounted if material was identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.4 GID-2669835 ACCOUNTING DIALOG (SR0070.1.3)

Data available per accounting step:

- **Identified** quantity and **UoM** toggle button (both read-only)
- **Consumed** quantity and **UoM** toggle button

- **Wasted** quantity and **UoM** toggle button (accessible according to **Calculation configuration (SR0070.8.3)** process parameter [\(GID-2671975\)](#))
- **Sampled** quantity and **UoM** toggle button
- **Returned** quantity and **UoM** toggle button (accessible according to **Calculation configuration (SR0070.8.3)** process parameter [\(GID-2671975\)](#))
- **Account** button
- **Cancel** button
- Phase action signature panel
(only if a phase action signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.5 GID-2669836 ACCOUNTING DIALOG - SINGLE SUBLOT (SR0070.1.3.1)

If, in the Table of materials (SR0070.1.2) [\(GID-2669834\)](#), a single subplot has been selected for accounting, the following data can be provided:

- **Consumed** quantity
- **Sampled** quantity
- **Wasted** quantity or **Returned** quantity (depends on **Calculation configuration (SR0070.8.3)** process parameter [\(GID-2671975\)](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.6 GID-2669837 ACCOUNTING DIALOG - CONSUME ALL (SR0070.1.3.2)

If, in the Table of materials (SR0070.1.2) [\(GID-2669834\)](#), a single batch, material item, or multiple sublots have been selected for accounting, the dialog opens in a **Consume all** mode. The **Identified** quantities are taken over as **Consumed** quantities. No quantities can be entered manually.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.7 GID-2669838 COMPLETED MODE (SR0070.1.5)

1. Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
(taken from Instruction (SR0070.8.1) process parameter [\(GID-2671969\)](#))
3. **Refresh** button (disabled).
4. **Account** button (disabled).
5. List of materials available for accounting (Table of materials (SR0070.1.2) [\(GID-2669834\)](#))
(taken from material input parameters (SR0070.6.1) [\(GID-2669844\)](#))
6. **Continue** and **Done (Stop)** option buttons (keep last selection, both disabled)
The buttons are only visible in case the **Enable loop** (SR0070.8.6) process parameter [\(GID-2671972\)](#) is set to **Yes**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop** (SR0070.8.8) process parameter [\(GID-2671973\)](#) is enabled.
7. **Enable** button (disabled).
The button is not visible in case a phase completion signature was configured during authoring.
The button is only visible in case the **Enable loop** (SR0070.8.6) process parameter [\(GID-2671972\)](#) is set to **No**.
8. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2 Representation in Navigator (SR0070.4+)

The Navigator provides the following details:

4.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
 - Example:
Account materials

4.1.2.2 GID-2669840 INFORMATION COLUMN (SR0070.4.1)

- <Continue, Stop, or Done> representing the content of the **Result** (SR0070.9.1) output variable [\(GID-2668425\)](#).
 - Example: Continue

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2.3 ACTION COLUMN

- There are no actions available.

4.1.3 Representation in Sub-report (SR0070.5+)

The sub-report contains the following information:

4.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

4.1.3.2 GID-2669843 SUB-REPORT ELEMENTS (SR0070.5.1)

- Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
- Summary line per position with material identifier and short description, planned quantity, planned quantity limits (only if defined), and accounted quantities (**Consumed, Wasted, Sampled, Returned**).
- List of identified sublots and logistic units per material position, including batch identifier and identified quantity
- Confirmed with **Continue** or **Done (Stop)**
Represents the content of the **Result (SR0070.9.1)** output variable ([GID-2668425](#)).
Only displayed in case the **Enable loop (SR0070.8.6)** process parameter ([GID-2671972](#)) is set to **Yes**.
- Signed actions
(only if a phase action signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2 Business Logic (SR0070.2+)

The phase implements the following business logic.

4.2.1 GID-2668407 Account material (SR0070.2.1)

- Function: Account pre-defined materials
- Trigger: Phase becomes active
- Postcondition: Pre-defined materials are accounted

Step	#	Description
Phase activation	10	Phase displays its user interface according to the Active mode (SR0070.1.1) layout (GID-2669833)
Operator starts accounting	20	Only if PharmaSuite is configured to communicate with Warehouse Management and, during the previous accounting, the Warehouse error (SR0070.3.1.1) user-triggered exception (GID-2670625) has not been recorded, phase displays the Missing Warehouse exception recording (SR0070.3.6.2) error message (GID-2668419) . The phase can only account material when the Warehouse error (SR0070.3.1.1) user-triggered exception (GID-2670625) has been recorded. Otherwise, phase displays the Accounting dialog (SR0070.1.3) form (GID-2669835) to declare consumed, wasted, sampled, and returned quantities.
Operator completed accounting dialog	30	Phase continues with the Determine accounting status (SR0070.2.5) function (GID-2668411) and sets the result as accounting status for the related material position.
	40	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred, phase displays the Warehouse error (SR0070.3.6.1) error message (GID-2668418) . The phase can only be completed when the Warehouse error (SR0070.3.1.1) user-triggered exception (GID-2670625) has been recorded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.2 GID-2668408 Detect unaccounted materials (SR0070.2.2)

- Function: Detect if there are unaccounted materials
- Trigger: Operator confirms phase
- Postcondition: Unaccounted materials are recorded as exception

Step	#	Description
Operator confirms phase (not with Continue or Stop)	10	According to Accounting check configuration (SR0070.8.2) process parameter (GID-2671970) , phase checks if there are no unaccounted materials left. If the check fails, phase creates the Unaccounted material (SR0070.3.2.1) system-triggered exception (GID-2670622) .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.3 GID-2668409 Unit procedure context (SR0070.2.3)

- Function: Define unit procedure context
- Trigger: Materials have been accounted
- Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that accounted materials are only recognized within the given unit procedure.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.4 GID-2668410 Phase completion (SR0070.2.4)

- Function: Completion of phase
- Trigger: Complete material accounting
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	<p>In case one or more locally accounted sublots were accounted from another phase instance, phase displays the Simultaneous accounting on same subplot (SR0070.3.4.1) information message (GID-2668417) of the warning type.</p> <p>In order to be completed, the phase requires all system-triggered exceptions to be recorded.</p> <p>Only if PharmaSuite is configured to communicate with Warehouse Management and a warehouse-related error has occurred during the last accounting, phase can only be completed when the Warehouse error (SR0070.3.1.1) user-triggered exception (GID-2670625) has been recorded. If the exception is not recorded, phase displays the Missing Warehouse exception recording (SR0070.3.6.2) error message (GID-2668419).</p>
Operator confirms phase (not with Continue or Stop)	20	<p>Phase determines the accounting status for all material input parameters (SR0070.6.1) process inputs (GID-2669844) with the Determine accounting status (SR0070.2.5) function (GID-2668411). If for any material input to check, the status is Undefined, Below tolerance or Above tolerance, phase creates the Quantity out of tolerance (SR0070.3.2.3) system-triggered exception (GID-2670623).</p> <p>If no exception is created or the created exception is recorded, the status of all positions with accounted material is set to Accounted and the Result (SR0070.9.1) output variable (GID-2668425) is set to DONE.</p>
Operator confirms phase (with Continue or Stop)	30	<p>If all exceptions are recorded, the Result (SR0070.9.1) output variable (GID-2668425) is set to CONTINUE or STOP, respectively.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.5 GID-2668411 Determine accounting status (SR0070.2.5)

- Function: Determine the accounting status for a material position
- Trigger: Operator accounts material or confirms phase (not with **Continue** or **Stop**)
- Postcondition: Accounting status is known

Step	#	Description
	10	If for the position to check, the planned quantity mode is configured as None at the material input parameters (SR0050.6.1) process inputs (GID-2669796) the status is not needed.
	20	<p>If for the position to check, the planned quantity mode is configured as As defined or As produced at the material input parameters (SR0050.6.1) process inputs (GID-2669796) the status is determined.</p> <p>If the planned quantity is not set or no material is identified, the result is Undefined, otherwise it is calculated:</p> <ul style="list-style-type: none"> ▪ The accounted quantity is calculated as a total value of all accounted sublots for a material position. If the Include sample and waste quantities (SR0070.8.7) process parameter (GID-2671974) is enabled: $accQty = consumedQty + SampledQty + WastedQty$ If the Include sample and waste quantities (SR0070.8.7) process parameter (GID-2671974) is not enabled: $accQty = consumedQty$ ▪ The planned quantity and its tolerances are retrieved from the related material input parameters (SR0050.6.1) process inputs (GID-2669796). $plannedRangeMin = planned\ quantity - lower\ tolerance$ $plannedRangeMax = planned\ quantity + upper\ tolerance$ ▪ $accQty < plannedRangeMin$: Below tolerance $accQty > plannedRangeMax$: Above tolerance else: In tolerance

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3 Recipe Parameters

The phase provides material input parameters as process inputs [\(GID-2668412\)](#) and process parameters [\(GID-2668413\)](#).

4.3.1 Process Inputs (SR0070.6+)

4.3.1.1 GID-2669844 MATERIAL INPUT PARAMETERS (SR0070.6.1)

The default material input parameters are available to define which materials can be accounted during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2 Process Parameters (SR0070.8+)

The following process parameters define the behavior of the phase.

4.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

4.3.2.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns. Default setting: 1 column.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

4.3.2.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

4.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

4.3.2.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the Instruction link definition process parameter (GID-2671968). Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

4.3.2.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the Link URL attribute. Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

4.3.2.3 BASIC PARAMETERS

4.3.2.3.1 GID-2671969 INSTRUCTION (SR0070.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. Restriction: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

4.3.2.4.1 GID-2671970 ACCOUNTING CHECK CONFIGURATION (SR0070.8.2)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Unaccounted material (SR0070.3.2.1)** system-triggered exception ([GID-2670622](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.4.2 GID-2671971 QUANTITY OUT OF TOLERANCE (SR0070.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Quantity out of tolerance (SR0070.3.2.3)** system-triggered exception ([GID-2670623](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.5 PROCESSING PARAMETER

4.3.2.5.1 GID-2671972 ENABLE LOOP (SR0070.8.6)

Attribute	Type	Comment
Enabled	Flag	Defines if the Continue/Done buttons will be available and the phase can be looped without accounting checks. Default setting: No .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.5.2 GID-2671973 ALLOW LOOP EXIT WITH STOP (SR0070.8.8)

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the Done button is replaced with a Stop button. This allows a loop exit with the same behavior as the Continue button. Default setting: No .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.5.3 GID-2671974 INCLUDE SAMPLE AND WASTE QUANTITIES (SR0070.8.7)

Attribute	Type	Comment
Enabled	Flag	Defines if the Quantity out of tolerance check against the planned quantity for the accounted quantity shall include besides the consumed quantity also the sampled and wasted quantities. Default setting: No .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.5.4 GID-2671975 CALCULATION CONFIGURATION (SR0070.8.3)

Attribute	Type	Comment
Result	Choice list	Defines whether the returned quantity or the wasted quantity is calculated. Return(ed) qty = Identified qty - Consumed qty - Sampled qty - Wasted qty Waste(d) qty = Identified qty - Consumed qty - Sampled qty - Returned qty Default setting: Return .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.6 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

4.3.2.6.1 GID-2671976 WAREHOUSE ERROR (SR0070.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.

See also **Warehouse error (SR0070.3.1.1)** user-triggered exception ([GID-2670625](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4 Exceptions (SR0070.3+)

The phase supports user-defined, user-triggered ([GID-2668415](#)), system-triggered ([GID-2668414](#)), and post-completion exceptions ([GID-2668416](#)) and their configuration by means of process parameters ([GID-2668413](#)).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

4.4.1 System-triggered Exceptions (SR0070.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

4.4.1.1 GID-2670622 UNACCOUNTED MATERIAL (SR0070.3.2.1)

Representation during exception handling:

- <Exception text>
(taken from **Accounting check configuration (SR0070.8.2)** process parameter ([GID-2671970](#))
<Number> sublots have not been accounted yet.
- Example:
Unaccounted materials.
2 sublots have not been accounted yet.

Step	#	Description
Operator triggers exception	10	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.2 GID-2670623 QUANTITY OUT OF TOLERANCE (SR0070.3.2.3)

If the planned quantity mode (defined with the **Identify material** phase ([GID-2670623](#))) of any material position assigned to this phase is **As produced** or **As defined** and the identified quantity is not within the range of the planned quantity and its tolerance or the planned quantity is 0, an exception is raised.

Representation of the exception:

- <Exception text>
(taken from **Quantity out of tolerance (SR0070.8.5)** process parameter ([GID-2671971](#))
The following positions are out of tolerance or cannot be checked:
Material: <material identifier>; Planned quantity: <planned quantity [lower limit .. upper limit]>;
Accounted quantity: <accounted quantity>
Material: <material identifier>; Planned quantity: <planned quantity>; Accounted quantity: <accounted quantity>
Material: <material identifier>; Planned quantity: undefined; Accounted quantity: <accounted quantity>
- Example:
Unexpected accounted quantities.
The following positions are out of tolerance or cannot be checked:
Material: D130-01; Planned quantity: 100.0 kg [99.0 kg .. 105.0 kg]; Accounted quantity: 50.000 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.3 GID-2670624 MULTIPLE EXCEPTIONS (SR0070.3.2.4)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2 User-triggered Exceptions (SR0070.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

4.4.2.1 GID-2670625 WAREHOUSE ERROR (SR0070.3.1.1)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- **Warehouse error (SR0070.3.6.1)** error message ([GID-2668418](#))

Representation of the exception:

- Instruction:
Confirm to record the warehouse error.
Confirm button.
- <Exception text>
(taken from **Warehouse error (SR0070.8.4)** process parameter ([GID-2671976](#)))
A warehouse error has occurred while accounting material.
<Error message from the warehouse system>
- Example:
Document warehouse error
A warehouse error has occurred while accounting material.
<Error message from the warehouse system>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.2 GID-2670626 WAREHOUSE ERROR - LOGIC (SR0070.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the Warehouse error (SR0070.8.4) process parameter (GID-2671976).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

4.5 Information Messages (SR0070.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

4.5.1 GID-2668417 Simultaneous accounting on same subplot (SR0070.3.4.1)

UI text	Comment
One or more of the sublots you have accounted were modified afterwards. Please review the modifications. Modified subplot(s): <list of subplot identifiers>	Message pack: PhaseProductAccountMaterial<version> Message ID: ModificationsDetectedOnComplete
One or more of the sublots you have accounted were modified afterwards. Please review the modifications. Modified subplot(s): <list of subplot identifiers>	Message pack: PhaseProductAccountMaterial<version> Message ID: ModificationsDetectedOnRefresh

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.6 Questions

There are no questions available.

4.7 Decisions

There are no decisions available.

4.8 Error Messages (SR0070.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

4.8.1 GID-2668418 Warehouse error (SR0070.3.6.1)

UI text	Comment
A warehouse error has occurred while accounting material. <Error message from the warehouse system>	Message pack: PhaseProductAccountMaterial<version> Message ID: AccountSublotsWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.2 GID-2668419 Missing warehouse exception recording (SR0070.3.6.2)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: PhaseProductMaterial<version> Message ID: SignWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.3 GID-2668420 Accounting already closed for selection (SR0070.3.6.3)

UI text	Comment
Cannot account the selected subplot(s), since it has/they have already been accounted.	Message pack: PhaseProductAccountMaterial<version> Message ID: AllRowsAccountedTxt

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9 Output Variables (SR0070.9+)

The following output variables are available to reference the phase's output.

4.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

4.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

4.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

4.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

4.9.5 GID-2668425 Result (SR0070.9.1)

- Data type: String
- Values: CONTINUE, STOP, DONE
- Usage: The output variable provides the result of the phase processing:
 - The value is CONTINUE if the phase was completed with **Continue**.
 - The value is STOP if the phase was completed with **Stop**.
 - The value is DONE if the phase was completed with **Done** or the **Enable loop (SR0070.8.6)** process parameter [\(GID-2671972\)](#) is not set to **Yes**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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5 Produce Material Phase (SR0060+)

The **Produce material** phase allows an operator to produce intra materials or the final product during recipe execution.

Example use cases are:

- **Produce intra materials**
The intra materials produced in a processing step will be used in a subsequent processing step. Create the sublots of the intra materials and print their labels. Now, the intra materials are prepared for identification in the next processing step.
- **Produce intra materials with defined quality status**
The quality status of the intra materials must be **Released**. This requirement can be defined and will be assigned to the produced sublots.
- **Produce final product**
For final products, the quantity can be declared and labels printed per subplot. Then, the product can be delivered to the warehouse.
- **Produce final product using packaging levels**
The packaging levels defined for an ERP BOM or a material are visible during phase execution in order to support the operator when he enters the produced quantity. In case **Blister** and **Shipping carton** packaging levels are defined, he can quantify the quantity in the packaging levels even if the outgoing material is accounted in each.
- **Reprint a subplot label**
If there was a problem during label printing that renders the printed labels unusable, the required labels can be printed again.

The number of produced sublots and their material identifiers are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668428](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2668036](#))(e.g. label reprint).

After completion the phase displays the produced material with the following data in the Execution Window:

- batch identifiers
- planned quantity
- already produced quantity

- subplot identifier and quantity (of newly produced sublots)
- number of sublots
or
packaging level data.

The Navigator displays the quantity produced during this run and provides access to the post-completion exceptions.


Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot t g kg

Total t g kg

Limits: [1,009.0 g .. 1,011.0 g]

[Refresh](#) 

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-01	Sonolin 100 mg premix			1,010.0 g	0 g	


☒ Continue ☐ Done [Confirm](#) 

Figure 12: Produce material during execution


Move verified output material to one or more sublots.

Number of sublots

Quantity per subplot t g kg

Total t g kg

Limits: [1,009.0 g .. 1,011.0 g]

[Refresh](#) 

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-01	Sonolin 100 mg premix	BX462		1,010.0 g	500 g	

D130-01: SL00000434 contaminated, re-produce 250.0 g.



☒ Continue ☐ Done [Confirm](#) 

Figure 13: Produce material during execution

Move packaged product to one or more sublots.

<input type="text"/>	Pallet(s)	(LU)	containing	5 shipping cartons =	0 ea
<input type="text" value="2"/>	Shipping carton(s)	(SL)	containing	20 bundles =	2,000 ea
<input type="text" value="15"/>	Bundle(s)		containing	5 folding cartons =	750 ea
<input type="text"/>	Folding carton(s)		containing	1 blister =	0 ea
<input type="text"/>	Blister(s)		containing	10 tablets =	0 ea
<input type="text"/>	Tablet(s)			=	0 ea
					Total (tablets) = 2,750 ea

Limits: [5,500 ea .. 5,500 ea]



Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-30	Sonolin retard 100 mg tablets			5,500 ea	0 ea	



☒ Continue ☐ Done 

Figure 14: Produce material during execution

Move packaged product to one or more sublots.

<input type="text"/>	Pallet(s)	(LU)	containing	5 shipping cartons =	0 ea
<input type="text" value="1"/>	Shipping carton(s)	(SL)	containing	20 bundles =	1,000 ea
<input type="text" value="2"/>	Bundle(s)		containing	5 folding cartons =	100 ea
<input type="text"/>	Folding carton(s)		containing	1 blister =	0 ea
<input type="text"/>	Blister(s)		containing	10 tablets =	0 ea
<input type="text"/>	Tablet(s)			=	0 ea
					Total (tablets) = 1,100 ea

Limits: [5,500 ea .. 5,500 ea]



Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Produced quantity	Sublot quantity
D130-30	Sonolin retard 100 mg tablets			5,500 ea	0 ea	


☐ Continue ☒ Stop 

Figure 15: Produce material during execution

5.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668426](#)), in the Navigator ([GID-2668427](#)), and in the sub-report ([GID-2668428](#)).

5.1.1 Representation during Execution (SR0060.1+)

The representation during execution depends on the phase mode.

5.1.1.1 GID-2670627 PREVIEW MODE (SR0060.1.3)

1. <Instruction text>
(taken from **Instruction (SR0060.8.1)** process parameter ([GID-2671981](#)))
2. Data of produced quantities (in the unit of measure of the target material):
 - **No packaging levels are defined**
 - Text box for the number of sublots (disabled).
 - Text box for the quantity per subplot (disabled).
 - **UoM** button (disabled).
 - **Packaging levels are defined**
 - List of defined and visible packaging levels
 - Text box (disabled) and information about contained number within the next lower level (taken from material output parameters (SR0060.7.1) ([GID-2670636](#)) and the packaging levels-specific Master Recipe - Header Attributes (SR3146.9.3.1) in "Functional Requirement Specification Recipe and Workflow Management" [A2] ([GID-2668043](#)))
3. Quantity summary information
4. **Refresh** button (disabled)
5. List of materials available for production (Table of materials (SR0060.1.2) ([GID-2670629](#)))
(taken from material output parameters (SR0060.7.1) ([GID-2670636](#)))
6. Material-related comment to execution
(only visible if comment is maintained for the order step output and if the order step is reactivated)
7. **Continue** and **Done (Stop)** option buttons (both disabled)
The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0060.8.11)** process parameter ([GID-2671984](#)) is enabled.
8. **Confirm** button (disabled).
9. Phase completion signature panel
(only if a phase completion signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.2 GID-2670628 ACTIVE MODE (SR0060.1.1)

1. Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
(taken from **Instruction (SR0060.8.1)** process parameter [\(GID-2671981\)](#))
3. Data of produced quantities (in the unit of measure of the target material):
 - **No packaging levels are defined**
 - Text box for the number of sublots
 - Text box for the quantity per subplot
 - **UoM** toggle button
 - **Packaging levels are defined**
 - List of defined and visible packaging levels
 - Text box and information about contained number within the next lower level
(taken from material output parameters (SR0060.7.1) [\(GID-2670636\)](#) and, in case the output material is equal to the target material of the order, the packaging levels-specific Master Recipe - Header Attributes (SR3146.9.3.1) in "Functional Requirement Specification Recipe and Workflow Management" [A2] [\(GID-2668043\)](#))
4. In case the **Planned quantity mode** of the material output parameters (SR0060.7.1) [\(GID-2670636\)](#) is set to **As defined**, phase displays the range for the produced quantity:
Limits: [<lower limit> .. <upper limit>]
5. In case a target subplot status is defined:
 - Sublot status: <defined target subplot status>
6. Quantity summary information
7. **Refresh** button
8. List of materials available for production (Table of materials (SR0060.1.2) [\(GID-2670629\)](#))
(taken from material output parameters (SR0060.7.1) [\(GID-2670636\)](#))
9. Material-related comment to execution
(only visible if comment is maintained for the order step output and if the order step is reactivated)
10. **Continue** and **Done (Stop)** option buttons
(**Continue** selected)
The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0060.8.11)** process parameter [\(GID-2671984\)](#) is enabled.

11. **Confirm** button.

12. Phase completion signature panel

(only if a phase completion signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.3 GID-2670629 TABLE OF MATERIALS (SR0060.1.2)

Data available per subplot:

- Material ID (taken from material output parameters (SR0060.7.1) ([GID-2670636](#)))
- Material short description (taken from material output parameters (SR0060.7.1) ([GID-2670636](#)))
- Batch ID of material to be produced
- Planned quantity (taken from material output parameters (SR0060.7.1) ([GID-2670636](#)))
- Produced quantity (total)
- List of sublots produced with this phase instance including quantities

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.4 GID-2670630 COMPLETED MODE (SR0060.1.4)

1. Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
(taken from **Instruction (SR0060.8.1)** process parameter ([GID-2671981](#)))
3. Data of produced quantities (in the unit of measure of the target material):
 - **No packaging levels are defined**
 - Text box for the number of sublots (disabled).
 - Text box for the quantity per subplot (disabled).
 - **UoM** button (disabled).
 - **Packaging levels are defined**
 - List of defined and visible packaging levels

- Text box (disabled) and information about contained number within the next lower level (taken from material output parameters (SR0060.7.1) [\(GID-2670636\)](#) and, in case the output material is equal to the target material of the order, the packaging levels-specific Master Recipe - Header Attributes (SR3146.9.3.1) in "Functional Requirement Specification Recipe and Workflow Management" [A2] [\(GID-2668043\)](#))
- 4. In case a target subplot status is defined:
 - Sublot status: <defined target subplot status>
- 5. Quantity summary information
- 6. **Refresh** button (disabled).
- 7. List of materials available for production (Table of materials (SR0060.1.2) [\(GID-2670629\)](#) (taken from material output parameters (SR0060.7.1) [\(GID-2670636\)](#))
- 8. Material-related comment to execution
(only visible if comment is maintained for the order step output and if the order step is reactivated)
- 9. **Continue** and **Done (Stop)** option buttons
(Used option button selected, both disabled)
The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0060.8.11)** process parameter [\(GID-2671984\)](#) is enabled.
- 10. **Confirm** button (completed).
- 11. Phase completion signature panel
(disabled and only if a phase completion signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2 Representation in Navigator (SR0060.4+)

The Navigator provides the following details:

5.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
 - Example:
Verify coating output

5.1.2.2 GID-2670632 INFORMATION COLUMN (SR0060.4.1)

- <Overall produced quantity with this phase instance>
 - Example: 980 ea

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2.3 GID-2670633 ACTION COLUMN (SR0060.4.2)

- Reprint, reprints a subplot label.
- Cancel, cancels the production of a subplot.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.3 Representation in Sub-report (SR0060.5+)

The sub-report contains the following information:

5.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

5.1.3.2 GID-2670635 SUB-REPORT ELEMENTS (SR0060.5.1)

- Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)
- Material: <identifier> / <short description>
- Planned and produced quantity (overall)
- Only in case packaging levels are defined:
 - Packaging levels with entered values (if any)
- List of sublots produced with this phase instance including quantities
- Material-related comment to execution (only visible if comment was visible during execution and if the order step was reactivated, i.e. was maintained for the order step output at that time)

Only in case the phase was completed with the **Done** option:

- List of sublots produced with all instances of this phase and operation including quantities

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2 Business Logic (SR0060.2+)

The phase implements the following business logic.

5.2.1 GID-2668429 Produce material (SR0060.2.1)

- Function: Produce pre-defined material
 - No packaging levels are defined
see **Produce material without packaging levels (SR0060.2.1.1)** function ([GID-2668430](#))
 - Packaging levels are defined
see **Produce material with packaging levels (SR0060.2.1.2)** function ([GID-2668430](#))
 - Trigger: Phase becomes active
 - Postcondition: Pre-defined material is produced

Step	#	Description
Phase activation	10	Phase displays its user interface according to the Active mode (SR0060.1.1) layout (GID-2670628).
	20	Phase checks if the defined target subplot status is valid. If not, phase displays the Target subplot status invalid (SR0060.3.6.7) error message (GID-2668450).
	30	<p>It checks if packaging levels are defined either</p> <ul style="list-style-type: none"> ▪ on material level of the output material or ▪ on ERP BOM (master recipe) level and the output material is equal to the target material of the order. <p>If so, it continues with the Produce material with packaging levels (SR0060.2.1.2) function (GID-2668431).</p> <p>Otherwise it continues with the Produce material without packaging levels (SR0060.2.1.1) function (GID-2668430).</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.2 GID-2668430 Produce material without packaging levels (SR0060.2.1.1)

Step	#	Description
Operator entered data and cursor leaves box	10	Based on the Number of sublots and Quantity per subplot , phase calculates and displays the updated quantity summary.
Operator confirms phase	20	<p>The phase performs the following checks:</p> <ul style="list-style-type: none"> ▪ The Confirm after warehouse error (SR0060.2.8) function (GID-2668437) checks if there are warehouse error-related exceptions that have not been recorded. ▪ In case the status of the output material was set to a final state by a simultaneously or previously running phase, a system user-signed exception record with this information will automatically be added to the phase. Continue with step 58. ▪ In case the Done or Stop option button is selected: If the Number of sublots or Quantity per subplot data is not a positive number and not both fields are empty, phase displays the Invalid subplot data (SR0060.3.6.3) error message (GID-2668446). ▪ In case the Continue option button is selected: If the Number of sublots or Quantity per subplot data is not a positive number, phase displays the Invalid subplot data (SR0060.3.6.3) error message (GID-2668446). ▪ If the planned quantity is violated, phase displays the Check planned quantity (SR0060.3.2.3) system-triggered exception (GID-2670647). The planned quantity check is only executed if the Planned quantity mode is As defined. The range for the allowed quantity is calculated as follows: Lower tolerance = min (absolute lower tolerance value (recipe), relative lower tolerance value (recipe)) and Upper tolerance = min (absolute upper tolerance value (recipe), relative upper tolerance value (recipe)) If neither the absolute nor the relative tolerance value is defined in the recipe, the tolerance for this value is 0. If only the absolute or only the relative value is defined, the value that is not defined is ignored. In case the Done option button is selected, the calculated quantity must be in the following range of [planned quantity - lower tolerance .. planned quantity + upper tolerance]. In case the Continue or Stop option button is selected, the calculated quantity must be lower than or equal to the planned quantity + upper tolerance.

Step	#	Description
		<ul style="list-style-type: none"> If the single subplot check is enabled (Limit quantity to single subplot (SR0060.8.5) process parameter (GID-2671985)) and if more than one subplot is going to be produced, phase displays the Limit quantity to single subplot (SR0060.3.2.1.1) system-triggered exception (GID-2670644)
	30	The Create subplot (SR0060.2.2) function (GID-2668432) becomes active.
	40	The Assign storage location (SR0060.2.3) function (GID-2668434) becomes active.
	50	The Assign batch status (SR0060.2.5) function (GID-2668435) becomes active.
	55	The Unit procedure context (SR0060.2.4) function (GID-2668436) becomes active.
	57	The Produce material done (SR0060.2.7) function (GID-2668433) becomes active.
	58	The Unforeseen simultaneous execution checks (SR0060.2.9) function (GID-2668438) becomes active.
	60	Phase updates the output variables: <ul style="list-style-type: none"> The Result (SR0060.9.2) variable (GID-2668457) is set to CONTINUE if the phase was completed with Continue, to STOP if the phase was completed with Stop, and to DONE if the phase was completed with Done. The Sublot identifiers (SR0060.9.1) variable (GID-2668456) contains the identifiers of the created sublots.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.3 GID-2668431 Produce material with packaging levels (SR0060.2.1.2)

Step	#	Description
Phase activation	10	In case the unit of measure of the output material is not equal to the unit of measure configured with the Base unit of measure (SR0060.11.1) configuration key (GID-2668459) or there is no matching conversion factor defined for the output material, phase displays the UoM conversion not possible (SR0060.3.6.4) error message (GID-2668447) .

Step	#	Description
Operator entered value for a packaging level and cursor leaves box	20	Phase calculates and displays the updated quantity summary.
Operator confirms phase	30	<p>The phase performs the following checks:</p> <ul style="list-style-type: none"> ▪ The Confirm after warehouse error (SR0060.2.8) function (GID-2668437) checks if there are warehouse error-related exceptions that have not been recorded. ▪ In case the status of the output material was set to a final state by a simultaneously or previously running phase, a system user-signed exception record with this information will automatically be added to the phase. Continue with step 58. ▪ In case the Continue option is selected: A positive number must have been entered for at least one packaging level value. Otherwise, phase displays the Invalid subplot data (SR0060.3.6.3) error message (GID-2668446). ▪ If the planned quantity is violated, phase displays the Check planned quantity (SR0060.3.2.3) system-triggered exception (GID-2670647). The planned quantity check is only executed if the Planned quantity mode is As defined. The range for the allowed quantity is calculated as follows: Lower tolerance = min (absolute lower tolerance value (recipe), relative lower tolerance value (recipe)) and Upper tolerance = min (absolute upper tolerance value (recipe), relative upper tolerance value (recipe)) If neither the absolute nor the relative tolerance value is defined in the recipe, the tolerance for this value is 0. If only the absolute or only the relative value is defined, the value that is not defined is ignored. In case the Done option button is selected, the calculated quantity must be in the following range of [planned quantity - lower tolerance .. planned quantity + upper tolerance]. In case the Continue or Stop option button is selected, the calculated quantity must be lower than or equal to the planned quantity + upper tolerance. ▪ If the single subplot check is enabled (Limit quantity to single subplot (SR0060.8.5) process parameter (GID-2671985)) and if more than one subplot is going to be produced, phase displays the Limit quantity to single subplot (SR0060.3.2.1.1) system-triggered exception (GID-2670644).

Step	#	Description
		<ul style="list-style-type: none"> If the single logistic unit check is enabled (Limit quantity to single logistic unit (SR0060.8.6) process parameter (GID-2671986)) and if more material than one logistic unit can hold is going to be produced, phase displays the Limit quantity to single logistic unit (SR0060.3.2.2) system-triggered exception (GID-2670645).
	35	<p>In case the Continue, the Stop, or the Done option is selected and a value has been entered for at least one packaging value:</p> <ul style="list-style-type: none"> Phase calculates the number of sublots to be produced including quantity based on the Sublot inventory level and the entered values. If the Sublot inventory level is not defined, phase produces one sublot. The Create sublot (SR0060.2.2) function (GID-2668432) becomes active. Continue with step 40. <p>Otherwise continue with step 60.</p>
	40	The Assign storage location (SR0060.2.3) function (GID-2668434) becomes active.
	50	The Assign batch status (SR0060.2.5) function (GID-2668435) becomes active.
	55	The Unit procedure context (SR0060.2.4) function (GID-2668436) becomes active.
	57	The Produce material done (SR0060.2.7) function (GID-2668433) becomes active.
	58	The Unforeseen simultaneous execution checks (SR0060.2.9) function (GID-2668438) becomes active.
	60	<p>Phase updates the output variables:</p> <ul style="list-style-type: none"> The Result (SR0060.9.2) variable (GID-2668457) is set to CONTINUE if the phase was completed with Continue, to STOP if the phase was completed with Stop, and to DONE if the phase was completed with Done. The Sublot identifiers (SR0060.9.1) variable (GID-2668456) contains the identifiers of the created sublots. The LU quantity (SR0060.9.3) variable (GID-2668458) contains the produced quantity (only if the Logistic unit inventory level is defined).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.4 GID-2668432 Create subplot (SR0060.2.2)

- Function: Creation of sublots
- Trigger: Operator confirms phase
- Postcondition: Sublots are created

Step	#	Description
Operator provided data and confirms phase	10	Phase checks the number of sublots to be created. If the length of the Sublot identifiers (SR0060.9.1) output variable (GID-2668456) would be exceeded, phase displays the Too many sublots (SR0060.3.6.2) error message (GID-2668445) .
	15	The target subplot status is set to the value defined as target subplot status with the material output parameter. In case the Overwrite target subplot status (SR0060.8.10) process parameter (GID-2671983) is enabled, the target subplot status is replaced by the value set there.
	16	According the inheritance rule configuration at target subplot's material (part), the CCT TITR values are calculated with Worst Case Inheritance Rule or No Inheritance Rule (see (GID-3695977) and (GID-3632063) in Functional Requirement Specification Execution Framework [A1] (GID-2668043)) and set when the sublots are created.
	20	Phase creates sublots and prints a label for each produced subplot. In case the status of the output material was set to a final state by a simultaneously running phase, the phase stops creating sublots and a system user-signed exception record with this information will automatically be added to the phase. Only if PharmaSuite is configured to communicate with Warehouse Management and a warehouse-related error has occurred during subplot creation, phase displays the Warehouse error (SR0060.3.6.5) error message (GID-2668448) . The phase can only be completed when the Warehouse error (SR0060.3.1.2) user-triggered exception (GID-2670650) has been recorded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.5 GID-2668433 Produce material done (SR0060.2.7)

- Function: Produce material done
- Trigger: Operator confirms phase
- Precondition: **Done** option button is selected
- Postcondition: Status of the output material is set to a final state

Step	#	Description
Operator confirms phase (Done option button is selected)	10	<p>PharmaSuite updates the status of the output material position as follows:</p> <ul style="list-style-type: none"> ▪ In tolerance: produced quantity is within tolerances. ▪ Overweight: produced quantity is greater than upper tolerance. ▪ Underweight: produced quantity is less than lower tolerance. ▪ Done: no planned quantity is maintained. <p>The updated status is visible in the D Identify material phase in case of concurrent processing in combination with the D Identify material phase and Inline Weighing. See also "Functional Requirement Specification Dispense and Inline Weighing" [A3] (GID-2668043).</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.6 GID-2668434 Assign storage location (SR0060.2.3)

- Function: Assignment of storage location
- Trigger: New subplot has been created
- Postcondition: Storage location is assigned

Step	#	Description
Sublots have been created	10	Phase assigns the pre-defined storage location to each subplot, per configuration on work center level.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.7 GID-2668435 Assign batch status (SR0060.2.5)

- Function: Assignment of batch status
- Trigger: New batch has been created
- Precondition: No order-related batch exists yet for the product material
- Postcondition: Batch status is assigned

Step	#	Description
Unit procedure context has been defined	10	According to Batch definition (SR0060.8.2) process parameter (GID-2671982) , phase assigns a pre-defined batch status to the newly created batch. (Does not apply to already existing batches that have been defined on order level.)
	20	If no status is pre-defined, Quarantined is assigned as the default status.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.8 GID-2668436 Unit procedure context (SR0060.2.4)

- Function: Define unit procedure context
- Trigger: A new subplot is created
- Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that produced materials are only recognized within the given unit procedure.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.9 GID-2668437 Confirm after warehouse error (SR0060.2.8)

- Function: Completion of phase after warehouse error
- Trigger: Phase is completed after warehouse error
- Postcondition: All warehouse error-related exceptions are recorded

Step	#	Description
Phase checks if there are warehouse error-related exceptions that have not been recorded	10	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred during the last material production and the Warehouse error (SR0060.3.1.2) user-triggered exception link has not been recorded, phase displays the Missing Warehouse exception recording (SR0060.3.6.6) error message (GID-2668449) .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.10 GID-2668438 Unforeseen simultaneous execution checks (SR0060.2.9)

- Function: Unforeseen simultaneous execution checks
- Trigger: Operator confirms phase
- Precondition: Phase used in ETOs
- Postcondition: Unforeseen simultaneous execution results recorded

Step	#	Description
Operator confirms phase (ETO)	10	<p>Since the phase can run simultaneously in several ETOs, the following check is executed:</p> <ul style="list-style-type: none"> ▪ In case a planned quantity is defined and the produced quantity violates the upper tolerance that was not already recorded with the Check planned quantity (SR0060.3.2.3) system-triggered exception (GID-2670647), a system user-signed exception record with this information will automatically be added to the phase. <p>In case an exception was recorded automatically due to the above described quantity violation or the output material was set to a final state by a simultaneously running phase, the phase displays the Unforeseen simultaneous execution result (SR0060.3.6.8) error message (GID-2668451).</p>

Step	#	Description
	20	If the output material is set to a final state, the phase will be completed with the Done option, but without the sub-report section listing all sublots produced with all instances of this phase and operation.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3 Recipe Parameters

The phase provides material output parameters as process outputs ([GID-2668439](#)) and process parameters ([GID-2668440](#)).

5.3.1 Process Outputs (SR0060.7+)

5.3.1.1 GID-2670636 MATERIAL OUTPUT PARAMETERS (SR0060.7.1)

The default material output parameters are available to define which material can be produced during execution.

Quantity definitions of the material output parameters are populated to the **Table of materials (SR0060.1.2)** list ([GID-2670629](#)) that is displayed during execution. This includes the reflection of quantity-related calculations during order explosion.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2 Process Parameters (SR0060.8+)

The following process parameters define the behavior of the phase.

5.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

5.3.2.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns. Default setting: 1 column.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

5.3.2.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

5.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

5.3.2.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the Instruction link definition process parameter (GID-2671980). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

5.3.2.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the Link URL attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

5.3.2.3 BASIC PARAMETERS

5.3.2.3.1 GID-2671981 INSTRUCTION (SR0060.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. Restriction: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.4 PROCESSING PARAMETER

5.3.2.4.1 GID-2671982 BATCH DEFINITION (SR0060.8.2)

Attribute	Type	Comment
Batch status	Choice list	Defines the batch status of the newly created batch. Default setting: Quarantined . Important: The batch status setting only applies to newly created batches, but not to already existing batches.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.4.2 GID-2671983 OVERWRITE TARGET SUBLOT STATUS (SR0060.8.10)

Attribute	Type	Comment
Enabled	Flag	Controls if the defined target subplot status of the Material output parameters (SR0060.7.1) process output (GID-2670636) will be overwritten by the subplot status selected with the Sublot status attribute. Default setting: No .
Sublot status	Choice list	Defines the target subplot status. Available settings: ---, Blocked , Quality Inspection , Unrestricted . Default setting: ---. Can be defined by information flow. The meaning, not the localized value, of the choice element value needs to be provided. For keeping the subplot status empty, set "null".

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.4.3 GID-2671984 ALLOW LOOP EXIT WITH STOP (SR0060.8.11)

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the Done button is replaced with a Stop button. This allows a loop exit with the same behavior as the Continue button. Default setting: No .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

5.3.2.5.1 GID-2671985 LIMIT QUANTITY TO SINGLE SUBLOT (SR0060.8.5)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. Default setting: No .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit quantity to single subplot (SR0060.3.2.1.1)** system-triggered exception ([GID-2670644](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5.2 GID-2671986 LIMIT QUANTITY TO SINGLE LOGISTIC UNIT (SR0060.8.6)

Applies only if packaging levels are defined and the **Logistic unit** inventory level is assigned to one of the packaging levels (independent of the visibility of this packaging level).

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. Default setting: No .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit quantity to single logistic unit (SR0060.3.2.2)** system-triggered exception ([GID-2670645](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5.3 GID-2671987 CHECK PLANNED QUANTITY (SR0060.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Check planned quantity (SR0060.3.2.3)** system-triggered exception ([GID-2670647](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.6 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

5.3.2.6.1 GID-2671988 WAREHOUSE ERROR (SR0060.8.9)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.

See also **Warehouse error (SR0060.3.1.2)** user-triggered exception ([GID-2670650](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.7 CONFIGURATION OF POST-COMPLETION EXCEPTIONS

5.3.2.7.1 GID-2671989 REPRINT (SR0060.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Reprint label (SR0060.3.3.1)** post-completion exception ([GID-2670652](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.7.2 GID-2671990 CANCEL SUBLLOT (SR0060.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None , Low , Low (mandatory comment) , Medium , Medium (mandatory comment) , High , High (mandatory comment) . Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Cancel subplot (SR0060.3.3.2)** post-completion exception ([GID-2670653](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4 Exceptions (SR0060.3+)

The phase supports user-defined, user-triggered ([GID-2668442](#)), system-triggered ([GID-2668441](#)), and post-completion exceptions ([GID-2668443](#)), and their configuration by means of process parameters ([GID-2668440](#))

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

5.4.1 System-triggered Exceptions (SR0060.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

5.4.1.1 GID-3077360 LIMIT QUANTITY TO SINGLE SUBLLOT (SR0060.3.2.1)

Representation of the exception:

- <Exception text>
(taken from **Limit quantity to single subplot (SR0060.8.5)** process parameter ([GID-2671985](#)))
The produced quantity (<produced quantity>) exceeds the quantity allowed for one subplot (<quantity of one subplot>).
- Example:
The produced quantity (100 kg) exceeds the quantity allowed for one subplot (50 kg).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.2 GID-2670644 LIMIT QUANTITY TO SINGLE SUBLLOT - LOGIC (SR0060.3.2.1.1)

- Trigger: Operator confirms phase
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.3 GID-2670645 LIMIT QUANTITY TO SINGLE LOGISTIC UNIT (SR0060.3.2.2)

Applies only if packaging levels are defined and the **Logistic unit** inventory level is assigned to one of the packaging levels (independent of the visibility of this packaging level).

Representation of the exception:

- <Exception text>
(taken from **Limit quantity to single logistic unit (SR0060.8.6)** process parameter ([GID-2671986](#)))
The produced quantity (<produced quantity>) exceeds the quantity allowed for one logistic unit (<quantity of one LU>).

- Example:
Only allowed to produce one logistic unit load.
The produced quantity (400 kg) exceeds the quantity allowed for one logistic unit (300 kg).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.4 GID-2670646 LIMIT QUANTITY TO SINGLE LOGISTIC UNIT - LOGIC (SR0060.3.2.2.1)

Applies only if packaging levels are defined and the **Logistic unit** inventory level is assigned to one of the packaging levels (independent of the visibility of this packaging level).

- Trigger: Operator confirms phase
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.5 GID-2670647 CHECK PLANNED QUANTITY (SR0060.3.2.3)

Representation of the exception:

- <Exception text>
(taken from **Check planned quantity (SR0060.8.7)** process parameter [\(GID-2671987\)](#))
 - In case the phase is completed and the planned quantity is exceeded:
The produced quantity (<produced quantity>) has already reached or exceeds the allowed range for the planned quantity (<planned quantity [lowest .. highest]>).
 - In case the phase was completed with **Done** and the planned quantity is not reached:
The produced quantity (<produced quantity>) is not yet within the allowed range for the planned quantity (<planned quantity [lowest .. highest]>).

▪ Example:

Planned quantity violation.

The produced quantity (500 kg) has already reached or exceeds the allowed range for the planned quantity (400 kg [390 kg .. 420 kg]).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.6 GID-2670648 CHECK PLANNED QUANTITY - LOGIC (SR0060.3.2.3.1)

- Trigger: Operator confirms phase
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.7 GID-2670649 MULTIPLE EXCEPTIONS (SR0060.3.2.4)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2 User-triggered Exceptions (SR0060.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

5.4.2.1 GID-2670650 WAREHOUSE ERROR (SR0060.3.1.2)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- **Warehouse error (SR0060.3.6.5)** error message ([GID-2668448](#))

Representation of the exception:

- Instruction:
Confirm to record the warehouse error.
Confirm button.
- <Exception text>
(taken from **Warehouse error (SR0060.8.9)** process parameter ([GID-2671988](#)))
 - A warehouse error has occurred while canceling sublots.
<Error message from the warehouse system>
 - A warehouse error has occurred while producing sublots.
<Error message from the warehouse system>
 - Example:
Document warehouse error
A warehouse error has occurred while producing sublots.
<Error message from the warehouse system>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.2 GID-2670651 WAREHOUSE ERROR - LOGIC (SR0060.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the Warehouse error (SR0060.8.9) process parameter (GID-2671988).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3 Post-completion Exceptions (SR0060.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

5.4.3.1 GID-2670652 REPRINT LABEL (SR0060.3.3.1)

The **Reprint label** exception allows an operator to reprint a subplot label from the Navigator after the completion of the phase.

Representation of the exception:

- Instruction:
To reprint a subplot label, enter the ID of the produced subplot.
Box for barcode input.
Confirm button.
- <Exception text>
(taken from **Reprint (SR0060.8.4)** process parameter [\(GID-2671989\)](#))
Label of < subplot identifier> subplot reprinted.
 - Example:
Label reprinted
Label of SL00008765 subplot reprinted.

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	20	Phase reprints label.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.2 GID-2670653 CANCEL SUBLLOT (SR0060.3.3.2)

The **Cancel subplot** exception allows an operator to set the quantity of a produced subplot to zero.

Representation during exception handling:

- Instruction:
To cancel a subplot, enter the ID of the produced subplot.
Box for barcode input.
Confirm button.

- Exception text:
 <Exception text>
 (taken from **Cancel subplot (SR0060.8.8)** process parameter [\(GID-2671990\)](#))
 <Sublot identifier> (<quantity>) subplot canceled.
- Example:
 Destroy the label of the subplot.
 SL000078 (20 ea) subplot canceled.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.3 GID-2670654 CANCEL SUBLLOT - LOGIC (SR0060.3.3.2.1)

- Trigger: Phase is completed, a subplot has been created before
- Postcondition: Sublot is canceled

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	20	Phase consumes total subplot quantity and marks the subplot as logically deleted . The produced quantity of the material output is reduced accordingly.
	30	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred during subplot cancelation, phase displays the Warehouse error (SR0060.3.6.5) error message (GID-2668448) and the Warehouse error (SR0060.3.1.2) user-triggered exception (GID-2670650) is automatically recorded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.5 Information Messages

There are no information messages available.

5.6 Questions

There are no questions available.

5.7 Decisions

There are no decisions available.

5.8 Error Messages (SR0060.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

5.8.1 GID-2668444 No sublots identified (SR0060.3.6.1)

UI text	Comment
Cannot proceed, since no sublots of the ingoing material(s) are currently identified.	Message pack: PhaseProductProduceMaterial<version> Message ID: NoOSI_Msg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.2 GID-2668445 Too many sublots (SR0060.3.6.2)

UI text	Comment
Cannot proceed, since the defined number of sublots (<number of sublots to produce>) exceeds the maximum number of sublots that can be produced in one phase run (<number of allowed sublots>).	Message pack: PhaseProductProduceMaterial<version> Message ID: TooManySublotsMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.3 GID-2668446 Invalid subplot data (SR0060.3.6.3)

UI text	Comment
Cannot proceed, since the number of sublots must be a positive number.	Message pack: PhaseProductProduceMaterial<version> Message ID: InvalidNumOfSublots_Txt
Cannot proceed, since the quantity per subplot must be a positive number.	Message pack: PhaseProductProduceMaterial<version> Message ID: InvalidQty_Txt
Cannot proceed, since no values for packaging levels have been entered.	Message pack: PhaseProductProduceMaterial<version> Message ID: NoPackagingLevelValues_Txt

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.4 GID-2668447 UoM conversion not possible (SR0060.3.6.4)

UI text	Comment
Cannot proceed, since the required unit of measure conversion is not defined for the output material. Please contact your data administrator.	Message pack: PhaseProductProduceMaterial<version> Message ID: UoMConversionNotPossible_Txt

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.5 GID-2668448 Warehouse error (SR0060.3.6.5)

UI text	Comment
A warehouse error has occurred while canceling sublots. <Error message from the warehouse system>	Message pack: PhaseProductProduceMaterial<version> Message ID: CancelSublotWarehouseError_Error
A warehouse error has occurred while producing sublots. <Error message from the warehouse system>	Message pack: PhaseProductProduceMaterial<version> Message ID: ProduceSublotWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.6 GID-2668449 Missing warehouse exception recording (SR0060.3.6.6)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: PhaseProductMaterial<version> Message ID: SignWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.7 GID-2668450 Target subplot status invalid (SR0060.3.6.7)

UI text	Comment
The subplot status parameter attribute contains an invalid value: <value defined by information flow>. Please use the Repair function to correct the issue.	Message pack: PhaseProductProduceMaterial<version> Message ID: InvalidSublotStatus

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.8 GID-2668451 Unforeseen simultaneous execution result (SR0060.3.6.8)

UI text	Comment
The output material position has been closed in the meantime.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteMeantime_Error This message can be combined with other messages.
Not all sublots have been produced.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteSomeSublotsProduced_Error This message is combined with other messages.
No sublots have been produced here.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteNoSublotsProduced_Error This message is combined with other messages.
The produced quantity exceeds the upper tolerance.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteOverweight_Error This message can be combined with other messages.
Phase run will be completed.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteStoppedProd_Error This message is combined with other messages.
The produced quantity exceeds the upper tolerance.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOSTROverweight_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9 Output Variables (SR0060.9+)

The following output variables are available to reference the phase's output.

5.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

5.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

5.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

5.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

5.9.5 GID-2668456 Sublot identifiers (SR0060.9.1)

- Data type: String
- Usage: The output variable provides a comma-separated list of identifiers of the created sublots.
The separator is configurable with the **OutputSeparator** configuration key.

For configuration details, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Guide Configuration and Extension" [A4] ([GID-2668043](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.6 GID-2668457 Result (SR0060.9.2)

- Data type: String
- Values: CONTINUE, STOP, DONE
- Usage: The output variable provides the result of the phase processing:

- The value is **CONTINUE** if the phase was completed with **Continue**.
- The value is **STOP** if the phase was completed with **Stop**.
- The value is **DONE** if the phase was completed with **Done**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.7 GID-2668458 LU quantity (SR0060.9.3)

- Data type: **MeasuredValue**
- Usage: The output variable provides the produced quantity for a maximum logistic unit load as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.10 Configuration Keys (SR0060.11+)

The following configuration keys are available to configure the phase's behavior.

5.10.1 GID-2668459 Base unit of measure (SR0060.11.1)

- **Phase/ProduceMaterial/BaseUnitOfMeasure**
- **Type:** String
- **Value:** ea
- **Description:** The countable unit of measure to be used for the calculation result in case packaging levels are defined.
If the unit of measure of the defined output material is not equal to the configured unit of measure, a conversion factor between the configured unit of measure and the unit of measure of the defined output material must be available.
- **Evaluated:** When the **Produce material** phase is started in the Production Execution Client.
- **Range:** Valid countable unit of measure.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E
A3	FT PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM009B-EN-E
A4	FT PharmaSuite Technical Guide Configuration & Extension - Volume 4	PSCEV4-GR011B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

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7 Document Information

The document information covers various data related to the document.

7.1 Approval


This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Jürgen Stieber	Technical Lead
Ignaz Wangler	Test Lead

7.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Identify Material	11.1
Account Material	11.0
Produce Material	11.1
Functional Requirement Specification	1.0

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8 Appendix A - Revision History

8.1 Updated Requirements

- [GID-2669789](#) Table of materials (SR0050.1.2)
- [GID-2668366](#) Identify material (SR0050.2.1)
- [GID-2668370](#) Phase completion (SR0050.2.7)
- [GID-2669800](#) Instruction (SR0050.8.1)
- [GID-2669821](#) Quantity out of tolerance (SR0050.3.2.9)
- [GID-2668403](#) Enable and Configure Treatment ID Support (SR0050.11.1)
- [GID-2669832](#) Preview mode (SR0070.1.4)
- [GID-2671969](#) Instruction (SR0070.8.1)
- [GID-2668432](#) Create subplot (SR0060.2.2)
- [GID-2671981](#) Instruction (SR0060.8.1)
- [GID-2668456](#) Sublot identifiers (SR0060.9.1)
- [GID-2668459](#) Base unit of measure (SR0060.11.1)

8.2 Added Requirements

- [GID-3296583](#) Failed TITR maximum threshold check
- [GID-3296573](#) Failed TITR warning threshold check
- [GID-3296582](#) TITR maximum threshold check
- [GID-3296571](#) TITR warning threshold check

8.3 Deleted Requirements

None

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